



5603.013.02 McKesson (Order to Show Cause)

## UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

	***************************************
In the Matter of	)
McKesson Corporation	)
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	PLEADINGS
	VOLUMET

NO.	DATE	FILED BY	DESCRIPTION
1	8/4/06	DEA	Order to Show Cause
2	9/1/06	HPM	Request for a Hearing
3	9/11/06	DEA	Order for Prehearing Statements
4	10/3/06	DEA	Government's Prehearing Statement
5	10/23/06	DEA	Ruling on Requested Extension
6	10/23/06	НРМ	Respondent's Motion for Extension of Time to File Prehearing Statement
7	10/27/06	НРМ	Respondent's Motion for a Second Extension of Time to File Prehearing Statement
8	10/27/06	DEA	Ruling on Requested Extension
9	11/3/06	HPM	Prehearing Statement
10	11/27/06	DEA	Prehearing Ruling
roud.	3/16/07	НРМ	Motion for Extension of Time to File Supplemental Prehearing Statements and Exchange Documentary Evidence
12	3/16/07	DEA	Ruling on Extension of Time

PLAINTIFFS TRIAL EXHIBIT P-00016\_00001



\$603.013.02 McKesson (Order to Show Cause)

13	6/7/07	DEA	Memorandum to Counsel (Failure of both Parties to File	
			Supplemental Prehearing Statements – Possibly	
			Terminating Proceedings)	
14	6/7/07	DEA	Memorandum to Counsel (Not Terminating Proceedings)	
15	6/12/07	DEA	Government Supplemental Prehearing Statement	
			**************************************	
16	6/13/07	HPM	Motion To File Supplemental Prehearing Statement; Supplemental	
			Prehearing Statement Of McKesson Corporation	
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17	6/25/07	DEA	Consent Motion to Reschedule Hearing Dates	
18	6/26/06	DEA	Memorandum to Counsel and Order	
19	9/10/07	DEA	Memorandum to Counsel	
20	10/12/07	HPM	Joint Motion for Extension of Time to File Supplemental	
			Prehearing Statements and Exchange Documentary Evidence	
21	10/12/07	DEA	Ruling on Requested Extension	
22	10/19/07	DEA	Government Supplemental Prehearing Statement	
23	10/22/07	DEA	Government Request That Subpoenas Be Issued For The	
			Appearance And Testimony Of Witness	
24	10/22/07	DEA	Letter re: Subpoenas that had been Issued for Walker and	
			Mahoney	
25	10/23/07	DEA	Letter requesting Lists of Attendees	
26	10/23/07	DEA	Letter re Hearing Schedule	
27	10/23/07	DEA	Subpoenas to William Mahoney, Donald Walker	
28	10/24/07	DEA	Letter to William Mahoney, Donald Walker Explaining Subpoena	
29	10/25/07	DEA	Request for a Subpoena for Michael Mapes	
30	10/25/07	DEA	Letter re Michael Mapes Subpoena	
31	10/26/07	DEA	Settlement Offer	
32	11/1/07	DEA	Letter re Copies of Transcript	
33	11/7/07	DEA	Letter requesting List of Attendees	
34	11/7/07	DEA	Letter re Hearing Schedule	
35	11/19/07	HPM	Letter: Re Proposed Settlement	
36	11/19/07	DEA	Letter: Re Proposed Settlement	
37	11/23/07	DEA	Order: Request for Stay Granted (November 19, 2007)	
38	11/23/07	DEA	Order: Request for Stay Granted (November 20, 2007)	
39	12/17/07	DEA	Memorandum to Counsel re Settlement Negotiations	
40	3/7/08	HPM	Consent Motion to Stay Administrative Hearing and Proceedings	





#### 5603.013.02 McKesson (Order to Show Cause)

41	3/7/08	DEA	Order: Hearing for 3/10-12/08 cancelled and Proceedings Stayed
	****		Indefinitely
42	5/1/08	DEA	Letter from Linden Barber Authorizing Changes as Agreed Upon
			by the Six USA's Offices (signed)
43	5/5/08	DEA	Settlement and Release Agreement and Administrative
			Memorandum of Agreement
44	6/2/08	DOJ	Subpoena to Garry Adam
45	6/6/08	HPM	Joint Motion to Terminate
46	6/6/08	DEA	Order Terminating Proceedings



U. S. Department of Justice
Drug Enforcement Administration

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www.dea.gov

Washington, D.C. 20537

AUG 0 4 2006

#### IN THE MATTER OF

McKesson Corporation dba McKesson Drug Company 1515 West Bella Vista Street Lakeland, Florida 33805

#### ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford McKesson Drug Company of Lakeland, Florida (McKesson-Lakeland), an opportunity to Show Cause before the Drug Enforcement Administration, (DEA) at a place and time to be determined, as to why the DEA should not revoke its Certificate of Registration, PM0000771, as a distributor of controlled substances, and deny any applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) and (e), for reason that its registration is inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(b) and (d), as evidenced by, but not limited to, the following:

- McKesson Corporation of San Francisco, California operates numerous nationwide Distribution Centers including the facility McKesson-Lakeland, which holds a DEA registration as a distributor of controlled substances at registered premises located in Lakeland, Florida.
- 2. Each person who is registered to distribute controlled substances is required to report acquisition and distribution transactions for Schedule II controlled substances and narcotic controlled substances in Schedule III. DEA utilizes the ARCOS system, which is an automated data acquisition program, for this purpose.
- 3. In an April 27, 2001 policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. Many Internet pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory online questionnaire or perfunctory telephone "consult" with a doctor, who has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Such rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice, and dispense

quantities of controlled substances far beyond what normal walk-in or mail order pharmacies dispense.

- 4. On September 1, 2005, DEA Office of Diversion Control Headquarters personnel held a briefing for corporate officials and counsel of McKesson Corporation. The presentation included information on the characteristics of Internet pharmacies and the nature of their illegal activities. The presentation included a discussion of the DEA Internet policy statement as well as identification of common practices and ordering patterns of these internet pharmacies. The briefing specifically identified problem states, including Florida, as well as problem drugs to include phentermine, alprazolam and the Schedule III narcotic- hydrocodone. DEA also identified one customer of the Lakeland facility (United Prescription Scrvices) whose ordering practices were suspicious.
- 5. Subsequently, DEA officials reviewed ARCOS reports for the period October 1, 2005, to January 31, 2006, and found that seven Florida pharmacies were still acquiring extraordinary quantities of hydrocodone. Despite its knowledge of suspicious internet practices, McKesson-Lakeland was engaged in a continuing practice of supplying hydrocodone to these seven pharmacies.
- 6. A specific review of McKesson-Lakeland's distribution of hydrocodone during the month of October 2005, indicated that it had approximately distributed 4.35 million tablets of hydrocodone to 898 different pharmacies. A breakdown of these distribution practices revealed that 486 pharmacy customers received less than 2,000 tablets; 306 pharmacies received 2000-5000 tablets; and 99 pharmacies received between 5,000 and 21, 200 tablets each.
- 7. During October 2005, the remaining seven pharmacy customers of McKesson-Lakeland, all located in the Tampa area, received the following number of hydrocodone tablets: Trelles Pharmacy (Trelles)-53,000, BiWise Drugs (Bi-Wise)-160,300, Universal RX (Universal)-254,700, United Prescription Service (United)-288,100, Accumed Rx (Accumed)-404,400, Medipharm Rx (Medipharm)-500,900, and Avee Pharmacy (Avee)-520,200.
- 8. A further review of ARCOS data for the full year 2005 indicated that Medipharm and Universal ranked sixth and ninth respectively in the nation for hydrocodone purchases. Furthermore, for the full year 2005, Medipharm, Universal, Avee, and United ranked number one through four for purchases of hydrocodone in the State of Florida.
- 9. McKesson-Lakeland submitted excessive purchase reports to DEA for the months October and November 2005. In that report, they indicated their self-imposed shipment parameters for 500 count bottles of hydrocodone in various strengths. Despite this, in October 2005 and again in November 2005, McKesson-Lakeland made six sales of hydrocodone to Accumed, Bi-Wise, and Trelles substantially in excess of these limits.
- 10. An analysis of ARCOS data regarding purchases made during the four month period October 2005 through January 2006, indicated that the national average and Florida average hydrocodone purchases was approximately 24,000 tablets per pharmacy. Over that same four month period, the seven Internet pharmacies received between 245,000

and 3.5 million tablets. Most of these hydrocodone tablets were acquired from McKesson-Lakeland.

- 11. Again, on January 3, 2006, DEA Office of Diversion Control Headquarters personnel held a meeting for corporate officials and counsel of McKesson Corporation to discuss the multi-million tablet distributions of hydrocodone to Tampa area pharmacies. At the time of the presentation, it was learned that McKesson-Lakeland had not been able to access the level of sales of generic hydrocodone products from their recordkeeping system for internal analysis.
- 12. DEA investigators later commenced an analysis of all reported purchases and purchase records of controlled substances to establish percentages of sales for the seven pharmacies. For the month January 2006, the percentage of sales that were hydrocodone sales for these seven pharmacies were as follows: Accumed-77.7%, Avee-79.7%, Bi-Wise-83.3%, Medipharm-87.6%, Trelles-41.3%, United-90.1%, and Universal-77%. These percentages of hydrocodone sales are clearly indicative of a large scale internet dispensing activity, and are far beyond the hydrocodone sale activities of a true walk-in pharmacy or mail order pharmacy.

The following procedures are available to McKesson-Lakeland in this matter:

- 1. Within 30 days after the date of receipt of this Order to Show Cause, you may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (See 21 C.F.R. § 1301.43(a)).
- 2. Within 30 days after the date of receipt of this Order to Show Cause, you may file with the Deputy Administrator a waiver of hearing together with a written statement regarding its position on the matters of fact and law involved. (See 21 C.F.R. §1301.43(c)).
- 3. Should you decline to file a request for a hearing or should you so file and fail to appear at the hearing, you shall be deemed to have waived the hearing and the Deputy Administrator may cancel such hearing, if scheduled, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (See 21 C.F.R. §§ 1301.43(d) and 1301.43(e)).

Correspondence concerning this matter, McKesson Corporation, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537.

oseph T. Rannazzisi

Deputy Assistant Administrator

Office of Diversion Control

Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges

#### REQUEST FOR HEARING

Any person desiring a hearing with respect to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

Hearing Clerk
Office of the Administrative Law Judges
Drug Enforcement Administration
Washington, D.C. 20537

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the perticular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant, or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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·		DATE 8112006		
	r, Lillian Olmo, Kenneth B NT ADMINISTRATION		~	
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## REPORT OF GOVERNMENT CONTACT Drug Operations Menual Exibit 55-39

12/8	1/98 Distribution Center Name and Number: Lakeland 195
TO:	Vice President Distribution Operations Director Distribution Quality
CC:	
N.	Gary Hilliard, Director of Regulatory Affairs, Arlington, TX (fax # 817-652-7699) Ina Trugman, Law Department, 34th Floor, San Francisco, CA Time and date of contact by government representatives: 8:25 am Friday August 11, 2006
2.	Name of government representative(s): Kenneth Boggess, Lillian Olmo, Deborah Butcher
3.	Name of government agency, division, and address at which representative(s) work(s):  Drug Enforcement Administration  4950 W. Kennedy Blvd.
	Tampa, FL 33609
4.	Purpose of contact: Delivery of Order to Show Cause document
5.	If tax is involved, state the nature of the tax, e.g., sales or real estate:
6.	Additional comments:
	Document attached
	8/11/06 Brian Westmoreland
***************************************	8/11/06 Brian Westmoreland  Date Signature

ATTACH COPIES OF ANY DOCUMENTS RECEIVED OR GIVEN

(7/2000)

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#### HYMAN, PHELPS & MCNAMARA, P.C.

JAMES R. PHELPS PAUL M. HYMAN ROBERT A. DORMER STEPHEN H. MCHAHARA ROGER C. THIES THOMAS SCARLETT JEFFREY N. GIBBS BRIAN J. DONATO FRANK J. SASINOWSKI PRINCIPE SO SAMPLE ! A. WES SIEGNER, JR. alan m. Kirschenbaum DOUGLAS EL FARQUHAR JOHN A. GILBERT, JR. MANN P. FLEDER MARC H. SHAPIRO Jeffrey N. Wasserstein DAVID B. CLISSOLD JOSEPHINE M. TOPPENTE

DIRECT DIAL (202) 737-4293

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Lew Judde

Drug Enforcement Administration

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DARA S. KATCHER\*
KURT R. KARST
CHRISTINE P. BUMP
BRIAN J. WESOLOSKI
NOELLE C. SITTHRUL\*
CARMELINA G. ALLIS\*

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CHERYL F. GRAHAM, NO. FCP

September 1, 2006

#### BY FACSIMILE/CONFIRMATION COPY BY HAND DELIVERY

Helen Farmer
Hearing Clerk
Office of the Administrative Law Judges
Drug Enforcement Administration
U.S. Department of Justice
600 Army-Navy Drive
Arlington, Virginia 22202

Re: Order to Show Cause, McKesson Corporation dba McKesson Drug Company, Lakeland, Florida

Dear Ms. Farmer:

On behalf of McKesson Corporation dba McKesson Drug Company ("McKesson") and pursuant to 21 C.F.R. §§ 1301.43(a) and 1316.47, the undersigned counsel herein requests a hearing on the Drug Enforcement Administration's ("DEA's") Order to Show Cause (Order) that was received at McKesson's Lakeland distribution center on August 11, 2006.

McKesson is registered with the DEA as a distributor of controlled substances (DEA No. PM0000771) at 1515 West Bella Vista Street, Lakeland, Florida. The Order provided notice of DEA's intent to revoke McKesson's DEA registration and deny any pending application for such registration, on the grounds that McKesson's continued registration is inconsistent with the public interest.

2503 MAIN STREET SUITE 760 IX-VINE, CALIFORNIA 92514 IX-439 553-7400 FAX: 19491 553-7433 4818 Emperor Boulevard Suite 400 Durham, North Carolina 27703 8891313-4750 Fax. 19181313-4751 Helen Farmer September 1, 2006 Page 2 HYMAN, PHELPS & MCNAMARA, P.C.

McKesson herein requests a hearing, pursuant to 21 C.F.R. §§ 1301.43(a) and 1316.47, on the issue of whether the continued registration of the above referenced DEA registration is inconsistent with the public interest. McKesson denies generally the allegations raised in the Order that its registration should be revoked or denied. In particular, denies DEA's assertion that McKesson was engaged in the continuing practice of supplying hydrocodone to pharmacies whose practices were suspicious.

All notices sent pursuant to this proceeding should be addressed to the attention of the undersigned.

Respectfully submitted

Jóhn A. Gilbæft, Jr

Counsel for McKesson Corporation

cc: Joseph T. Rannazzisi

Deputy Assistant Administrator Office of Diversion Control

Wayne Patrick

Office of Chief Counsel (CCD)

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#### UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### ORDER FOR PREHEARING STATEMENTS

The undersigned administrative law judge has been duly designated as the presiding officer in the above-captioned case.

Upon consideration of the Order to Show Cause herein and of the response thereto requesting a hearing, it is

ORDERED that the Government, no later than 4:00 p.m. eastern daylight time on October 3, 2006, and Respondent, no later than 4:00 p.m. eastern daylight time on October 24, 2006, file with the Hearing Clerk, in triplicate, and serve on each other, a written statement containing the following sections:

- 1. Issue(s). Statement of the perceived issues.
- 2. Stipulations. Proposed stipulations and admissions of fact.
- 3. Witnesses. Names and addresses of all witnesses whose testimony is to be presented; counsel for Respondent should note that if an agent of Respondent intends to testify, that agent must be listed as a witness, and a summary of the testimony as described below must be provided.
- 4. Summary of testimony. Brief summary of the testimony of each witness (counsel for the Government to indicate clearly each and every act, omission or occurrence upon which he relies in seeking to revoke Respondent's Drug Enforcement Administration Certificate of Registration as a distributor of controlled substances and deny any pending applications for renewal or modification; counsel for Respondent to indicate clearly each and every matter as to which he intends to introduce evidence in opposition to revocation and denial). The summaries are to state what the testimony will be rather than merely listing the areas to be covered. The parties are reminded that testimony not disclosed in the prehearing statements or pursuant to subsequent rulings is likely to be excluded at the hearing.
- 5. **Documents.** List of all documentary evidence, including affidavits and other exhibits to be offered in evidence, specifying the number of pages in each (Government counsel to include in his list, and submit with his prehearing

statement, a copy of the Certificate of Registration that is the subject of the Order to Show Cause). Each exhibit is to be numbered or lettered with the designation to be used at the hearing. Any exhibit of more than five pages shall have each page numbered.

- 6. Other matters. Any other matters that the parties consider relevant.
- 7. **Desired location.** Desired situs for the hearing, with a detailed statement of reasons justifying any location other than Arlington, Virginia.
- 8. Best estimate as to time required for presentation of own case.

All proceedings will be governed by the provisions of 21 C.F.R. §§ 1316.41 - 1316.68 (2006). The date of the hearing will be set subsequent to the filing of prehearing statements.

Dated: September 11, 2006

Mary Ellen Bittner

Administrative Law Judge

N.B. Attention is directed to 21 C.F.R § 1316.45 (2006) which provides that papers are "deemed filed upon receipt by the Hearing Clerk." The Hearing Clerk's address is:

Office of Administrative Law Judges Drug Enforcement Administration Washington, D.C. 20537

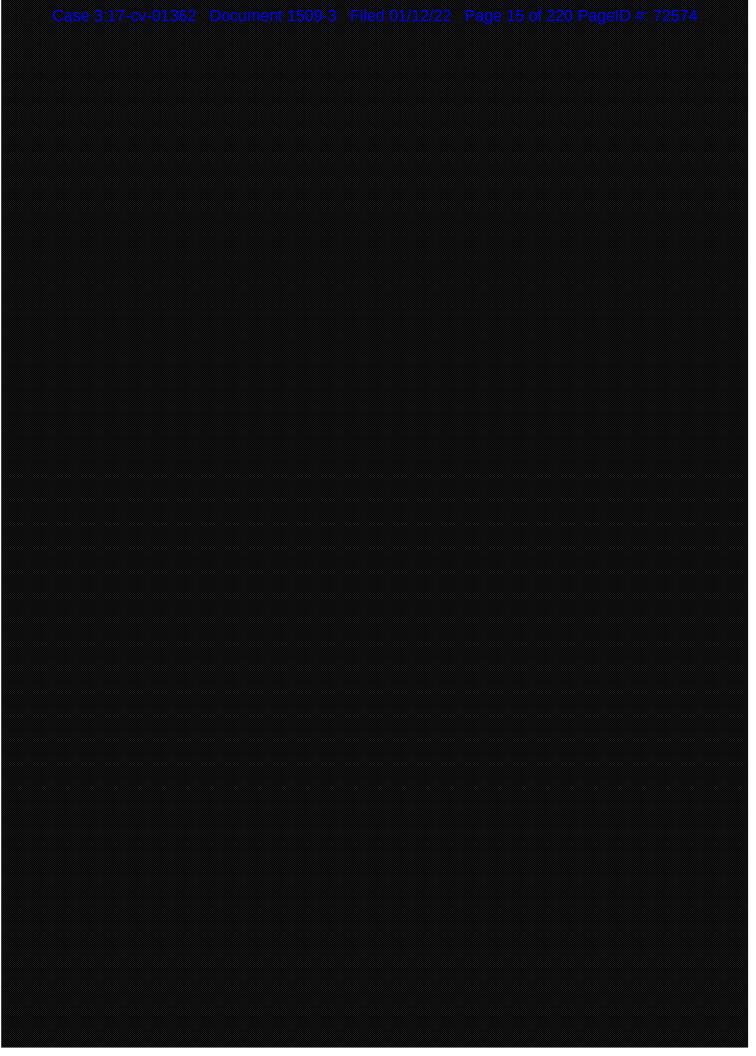
Respondent's counsel is cautioned that failure to file timely a prehearing statement as directed above may be considered a waiver of hearing and an implied withdrawal of a request for hearing. Both parties are cautioned that documents are to be filed in triplicate.

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on September 11, 2006, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Patricia A. Medico Secretary to Mary Ellen Bittner Administrative Law Judge

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# UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

MCKESSON CORPORATION

dba

MCKESSON DRUG COMPANY

Docket No. 06-23

GOVERNMENT'S PREHEARING STATEMENT

Wayne M. Patrick
Attorney, Office of Chief Counsel
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301
(202) 307-8010

#### In the Matter of: McKesson Drug Company (Respondent)

Pursuant to the September 11, 2006, Order of the Administrative Law Judge, the United States Department of Justice, Drug Enforcement Administration, by and through its undersigned attorney, hereby submits the following prehearing statement.

#### ISSUE

Whether the Drug Enforcement Administration (DEA) should revoke

McKesson Drug Company-Lakeland's (Respondent) (McKesson-Lakeland) DEA

Certificate of Registration, PM0000771, as a distributor pursuant to 21 U.S.C. §

824 (a) (4), any deny pending applications for renewal or modification of said

registration pursuant to 21 U.S.C. § 823 (f), for reason that its registration would

be inconsistent with the public interest as that term is used in 21 U.S.C. § 823 (f).

#### PROPOSED STIPULATIONS AND ADMISSIONS OF FACT

Hydrocodone is a Schedule III narcotic controlled substance pursuant to 21
 C.F.R. § 1308.13 (e).

#### PROPOSED WITNESSES

Diversion Investigator Scott Davis
Drug Enforcement Administration
Philadelphia Field Division
Philadelphia, Pennsylvania

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Diversion Investigator Shirley Scott Drug Enforcement Administration El Paso Field Division El Paso, Texas

Lisa Sullivan
Staff Coordinator, E-Commerce Section
Office of Diversion Control, DEA HQS
Arlington Virginia

Diversion Investigator Michael Mapes Chief, E-Commerce Section Office of Diversion Control, DEA HQS Arlington Virginia

#### PROPOSED TESTIMONY

#### Investigator Davis' Proposed Testimony

Investigator Scott Davis will testify that he is a Diversion Investigator with the DEA Philadelphia Field Division. He was assigned to participate in investigations involving the distribution of controlled substances to and from various internet pharmacy operations in the Tampa, Florida vicinity.

He will testify that McKesson Corporation of San Francisco, California operates numerous nationwide Distribution Centers including the facility McKesson-Lakeland, which holds a DEA Certificate of Registration, PM0000771, as a distributor of controlled substances at registered premises located in Lakeland, Florida.

A specific review of McKesson-Lakeland's distribution of hydrocodone during the month of October 2005, indicated that it had distributed 4.35 million tablets of hydrocodone to 898 different pharmacies. A breakdown of these

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distribution practices revealed that 486 pharmacy customers received less than 2,000 tablets; 306 pharmacies received 2000-5000 tablets; and 99 pharmacies received between 5,000 and 21,200 tablets each.

He will testify that during October 2005, the other seven pharmacy customers of McKesson-Lakeland, all located in the Tampa area, received the following number of hydrocodone tablets: Trelles Pharmacy (Trelles)- 53,000, Bi-Wise Drugs (Bi-Wise)-160,300, Universal RX (Universal)- 254,700, United Prescription Service (United)-288,100, Accumed Rx (Accumed)- 404,400, Medipharm Rx (Medipharm)-500, 900, and Avee Pharmacy (Avee)-520,200.

He will testify that DEA investigators later commenced an analysis of all reported purchases and purchase records of controlled substances to establish percentages of purchases attributable to hydrocodone for the seven pharmacies. For the month January 2006, the percentage of purchases that were hydrocodone for these pharmacies were as follows: Accumed-77.7%, Avee-79.7%, Bi-Wise-83.3%, Medipharm-87.6%, Trelles-41.3%, United-90.1%, and Universal-77%. These percentages of hydrocodone sales are clearly indicative of a large scale internet dispensing activity, and are far beyond the hydrocodone sale activities of a true walk-in pharmacy or mail order pharmacy.

#### Diversion Investigator Shirley Scott's Proposed Testimony

Investigator Scott will testify that she is a Diversion Investigator assigned to DEA El Paso Field Division. She will testify as to her training, experience and background as a Diversion Investigator.

She will testify that she was assigned to conduct an investigation of retail pharmacy registrant Accumed Rx, Inc. (Accumed) located at 3104 W. Waters Street, Suite 104B, Tampa, Florida 33614.

She will testify that on September 21, 2005, DEA Tampa, Florida Diversion Investigators visited Accumed. A discussion with management indicated that the pharmacy processed no walk-in prescriptions and utilized the Internet and facsimile exclusively in their dispensing business. A document review revealed that Accumed dispensed 877 nationwide prescriptions issued over two days by various doctors located in Puerto Rico and Florida. The inspection also showed that Accumed had over 700,000 dosage units of hydrocodone products in inventory. A review of records indicated that Accumed obtained predominantly a single controlled substance from multiple distributors. This practice has been observed in some cases as a method to evade the traditional methods used by DEA to monitor sales data from a retail pharmacy.

She will testify that Accumed dispensed more than fifty times as much hydrocodone as the average Florida retail pharmacy.

She will testify that in February 2006, DEA conducted an interview of a Florida physician who purportedly issued prescriptions to facilitate Accumed's

She will testify that these seven pharmacies in 2006 were all ranked among the highest distributors of hydrocodone in the State of Florida, and in several cases among the highest in the nation.

#### Diversion Investigator Michael Mapes' Proposed Testimony

Investigator Mapes will testify that he is a Diversion Investigator and the Chief of the DEA HQS Office of Diversion Control, E-Commerce Section. He will testify as to his training, experience and background as a Diversion Investigator and supervisor.

He will testify that The Controlled Substances Act (CSA) establishes a "closed system" of distribution that regulates the movement of controlled substance prescription medications from importation or manufacture through their delivery to the ultimate user patient via the dispensing, administering or prescribing pursuant to the lawful order of a practitioner. The regulations implementing the CSA explicitly describe the parameters of a lawful prescription as follows:

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 21 C.F.R. § 1306.04 (a)".

Prescriptions issued not in the "usual course of professional practice" are not "prescriptions" for purposes of the CSA and individuals issuing and filling such purported prescriptions are subject to the penalties for violating the CSA's

controlled substances provisions. CSA regulations establish certain responsibilities not only on individual practitioners who issue prescriptions for controlled substances, but also on pharmacists who fill them. A pharmacist's "corresponding responsibility" regarding the proper dispensing of controlled substances is explicitly described in 21 C.F.R. § 1306.04(a).

He will testify that in an April 21, 2001 policy statement, entitled, Dispensing and Purchasing Controlled Substances Over the Internet, 66 Fed. Reg. 21,181 (2001), DEA delineated certain circumstances in which prescribing over the Internet is unlawful. The policy provides, inter alia, that a controlled substance should not be issued or dispensed unless there was a bona fide doctor/patient relationship. Such a relationship required that the patient has a medical complaint, a medical history be taken, a physical examination performed, and some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed. The policy statement specifically explained that the completion of "a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship . . . " Id., at 21, 182-21,183.

He will testify that DEA has observed that while some consumers use Internet pharmacies for the convenience and privacy, others, including minor children, use the anonymity of the Internet to illegally procure controlled substances. Many Internet pharmacies bypass a legitimate doctor-patient relationship, usually by use of a cursory online questionnaire or perfunctory

telephone "consult" with a doctor, who has a contractual arrangement with the online pharmacy and is often paid on the basis of prescriptions issued. When the established safeguards of an authentic doctor-patient relationship are lacking, controlled substance prescription drugs can not only be misused, but also present potentially serious health risks to patients. Such rogue Internet pharmacies facilitate the easy circumvention of legitimate medical practice.

He will testify that these internet activities typically result in the dispensing of quantities of controlled substances far beyond what normal retail walk-in or true mail order pharmacies dispense.

Mr. Mapes will testify that he concludes that seven Tampa Florida area internet pharmacy operations have been distributing controlled substances in violation of Title 21 United States Code, Sections 829 and 841 (a) (1) in that the owners, pharmacists and employees all have direct knowledge that there is no legitimate physician/patient relationship established between the purported prescribing physician and the customers who order controlled substances directly through the websites. Each of these pharmacies received hydrocodone distributions from McKesson Lakeland.

He will testify that On September 1, 2005, DEA Office of Diversion

Control Headquarters personnel held a briefing for corporate officials and counsel of McKesson Corporation. The presentation included information on the characteristics of Internet pharmacies and the nature of their illegal activities. The presentation included the DEA internet policy statement as well as identification

of common practices and ordering patterns of these internet pharmacies. The briefing specifically identified problem states, including Florida, as well as problem drugs to include phentermine, alprazolam and the Schedule III narcotic-hydrocodone. Again, on January 3, 2006, DEA Office of Diversion Control Headquarters personnel held a meeting for corporate officials and counsel of McKesson Corporation to discuss the multi-million tablet distributions of hydrocodone to Tampa area pharmacies. At the time of the presentation, it was learned that McKesson Lakeland had not been able to access the level of sales of generic hydrocodone products from their recordkeeping system for their own internal analysis.

#### Pharmacy Expert's Proposed Testimony

The Government will present the testimony of an expert in the area of pharmacy practice, who will testify regarding his or her education, background, and experience. He or she will testify regarding the standard of practice and usual course of business observed by pharmacists and pharmacies when purchasing and dispensing controlled substances. The expert will testify regarding the concept of corresponding responsibility attaching to pharmacists when dispensing physicians' prescriptions.

The expert will also testify regarding the seven Tampa area Internet

Pharmacy's dispensing patterns with regard to the controlled substances they
handled. The expert will opine on the seven Internet pharmacy purchasing

patterns of all dangerous drugs as demonstrated by a review of distributor records and opine how this compares to known industry walk-in retail pharmacies and known industry mail order pharmacies. The expert will conclude that the seven pharmacy operations do not fit the model of a retail pharmacy and apparently is engaged in dispensing narcotics predominantly to individuals, in amounts not consistent with known demand to retail or mail order pharmacies and by use of prescription authorizations not sufficiently documented to ensure that the pharmacy meets its corresponding responsibility to ensure the substances are for legitimate therapeutic purposes and in the course of professional medical practice.

#### DOCUMENTARY EVIDENCE

- 1. Facsimile copy of DEA Certificate of Registration (McKesson-Lakeland)
- 2. Copy of DEA notice in 66 Fed. Reg. 21181, dated April 27, 2001
- 3. Charts- <u>Pharmacy Rankings for Hydrocodone</u>, October 2005-January 2006 (9 pages)
- 4. Charts- Accumed <u>ARCOS purchases from McKesson</u>, October 2005-January 2006 (9 pages)
- 5. Charts- Avee <u>ARCOS purchases from McKesson</u>, October 2005-January 2006 (9 pages)
- Charts- Bi-Wise <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- 7. Charts- Trelles ARCOS purchases from McKesson, October 2005-January 2006 (9 pages)
- 8. Charts- United <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)

- Charts- Universal <u>ARCOS purchases from McKesson</u>. October 2005-Janaury 2006 (9 pages)
- Charts- Medipharm <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- 11. Chart- Accumed Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 12. Chart- Avec Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 13. Chart- Bi-Wise Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 14. Chart-Trelles Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 15. Chart- United Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 16. Chart- Universal Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 17. Chart- Medipharm Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 18. Charts- State of Florida-Suppliers of Hydrocodone to Seven Florida Pharmacies October 31, 2005- January 31, 2006. (8 pages)
- 19. Accumed ARCOS purchases, October 2005-January 2006 (3 pages)
- 20. Spreadsheet-Mc Kesson Arcos Distribution October 1-31, 2005. (208 pages)
- 21. Spreadsheet-Mc Kesson Arcos Distribution 2006.
- 22. Compilation- Mc Kesson Distribution of Hydrocodone ...to Florida Pharmacies October 1-31, 2005 (16 pages)
- 23. Compilation- Mc Kesson Distribution of Hydrocodone by DEA Number Sort October 1-31, 2005 (19 pages)

- 24. Chart- Mc Kesson Hydrocodone Sales October 1-31, 2005. (2 pages)
- Spreadsheet-Mc Kesson Suspicious Purchase Report, October-November 2005. (27 pages)
- 26. DEA Compilation Sheet- Erroneous DEA number Identification in reports submitted by McKesson -2006.

#### OTHER MATTERS

None

#### DESIRED SITUS FOR THE HEARING:

Washington, D.C. (Arlington, VA)

#### TIME FOR PRESENTATION OF THE GOVERNMENT'S CASE

One and one-half day, exclusive of cross-examination.

Respectfully submitted,

Wayne M. Patrick

Attomey, Office of Chief Counsel

Dated: October 3, 2006

P-00016\_00027

#### CERTIFICATE OF SERVICE

On October 3, 2006, I sent via facsimile and mailed a copy of the foregoing, postage prepaid, to Counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman Phelps & McNamara, P.C., 700 13<sup>th</sup> Street N.W., Washington, D.C. 20005

Wayne M. Patrick

OCT-03-2006 14:42

P.01/15

#### CERTIFICATE OF SERVICE

On October 3, 2006, I sent via facsimile and mailed a copy of the foregoing, postage prepaid, to Counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman Phelps & McNamara, P.C., 700 13<sup>th</sup> Street N.W., Washington, D.C. 20005

Wayne M. Patrick

18/23/2006 15:19

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PAGE 01/02

#### U.S. Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tel. (202) 307-8188 Fax 307-8198

### **FAX TRANSMISSION**

Date:

October 23, 2006

To:

John A. Gilbert, Esq. Wayne Patrick, Esq.

Fax:

202-737-9329

7-4946

Re:

In the Matter of McKesson Corporation, d/b/a McKesson Drug Company

Docket No. 06-66

Sender:

Patricia Medico

Secretary to Mary Ellen Bittner Chief Administrative Law Judge

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Please see attached "Ruling on Requested Extension."

Attachment

#### UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### RULING ON REQUESTED EXTENSION

On October 23, 2006, counsel for Respondent filed a request for an extension of time to October 30, 2006, to file its prehearing statement in the above-captioned matter. Counsel for Respondent advised that counsel for the Government does not oppose the extension.

Inasmuch as it appears that no prejudice will result, Respondent's request is granted. Accordingly, Respondent may file its prehearing statement no later than 4:00 p.m. eastern standard time on October 30, 2006.

Dated: October 23, 2006

Mary Ellen Bittner

Administrative Law Judge

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on October 23, 2006, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Secretary to Mary Ellen Bittner Administrative Law Judge

P-00016 00031

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

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In The Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### RESPONDENT'S MOTION FOR EXTENSION OF TIME TO FILE PREHEARING STATEMENT

McKesson Corporation d/b/a McKesson Drug Company (Respondent), through the undersigned counsel, files this motion for an extension of time to file Respondent's Prehearing Statement in the above captioned matter. On September 11, 2006, the Administrative Law Judge (ALJ) issued an order requiring that the Government file its Prehearing Statement on or before October 3, 2006 and that Respondent file its Prehearing Statement on or before October 24, 2006. Respondent's counsel was served with a copy of the Government's Prehearing Statement on October 3, 2006.

In order to ensure that Respondent is able to address all of the issues in this matter, Respondent requests a brief extension of time until October 30, 2006 to file its Prehearing Statement. Respondent contacted Government counsel who represented that the Government does not object to the request for an extension.

1

Respectfully submitted,

John A Gilbert, Ir.

Hyman, Phelps & McNamara PC

700 Thirteenth Street, N.W.

Washington, D.C. 20005

(202) 737-5600

(202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: October 23, 2006

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 23, 2006, caused a copy of the foregoing to be delivered by facsimile and by hand to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be sent by facsimile and first class mail to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

R. Ian Kluge

## UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

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In The Matter of	)	
	)	
McKesson Corporation	)	Docket No. 06-66
d/b/a McKesson Drug Company	)	

#### RESPONDENT'S MOTION FOR A SECOND EXTENSION OF TIME TO FILE PREHEARING STATEMENT

McKesson Corporation d/b/a McKesson Drug Company (Respondent), through the undersigned counsel, files this motion for an second extension of time to file Respondent's Prehearing Statement in the above captioned matter. On September 11, 2006, the Administrative Law Judge (ALJ) issued an order requiring that the Government file its Prehearing Statement on or before October 3, 2006 and that Respondent file its Prehearing Statement on or before October 24, 2006. Respondent's counsel was served with a copy of the Government's Prehearing Statement on October 3, 2006. On October 23, 2006, Respondent requested an extension of time until October 30, 2006 to file its prehearing statement. The ALJ granted this request in an Order dated October 23, 2006.

Respondent herein requests a further extension until Friday, November 3, 2006 to submit its prehearing statement. Because of the press of other matters this week, Counsel for Respondent believes it will need additional time to make sure that it is able to

complete its Prehearing Statement. Respondent contacted Government counsel, Wayne Patrick, who stated that the Government does not object to this request for an extension.

Respectfully submitted,

John A. Gilbert, fr.

Hyman, Pholps & McNamara PC

700 Thirteenth Street, N.W.

Washington, D.C. 20005

(202) 737-5600

(202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: October 27, 2006

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 27, 2006, caused a copy of the foregoing to be delivered by facsimile and by hand to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be sent by facsimile and first class mail to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia, 22202

Arlington, Virginia 22202

Kathleen McKinley



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\*нот армитерін ро

CHERYL F. GRAHAM MD, FOP REDULATORY SCIENTIST

## **FACSIMILE TRANSMITTAL SHEET**

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John Gilbert

DATE:

October 27, 2006

TO:

Honorable Mary Ellen Bittner

FAX NO.:

(202) 307-8198

Wayne Patrick

(202) 307-4946

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LJ

PAGE 01/02

#### U.S. Department of Justice

Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 Tel. (202) 307-8188 Fax 307-8198

# FAX TRANSMISSION

Date:

October 27, 2006

To:

John A. Gilbert, Jr., Esq. Wayne M. Patrick, Esq.

Fax:

202-737-9329

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Re:

In the Matter of McKesson Corporation d/h/a McKesson Drug Company

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# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

#### RULING ON REQUESTED EXTENSION

On October 27, 2006, counsel for Respondent filed a request for a second extension of time, to November 3, 2006, to file its prehearing statement in the above-captioned matter. Counsel for Respondent advised that counsel for the Government does not oppose the extension.

Inasmuch as it appears that no prejudice will result, Respondent's request is granted. Accordingly, Respondent may file its prehearing statement no later than 4:00 p.m. eastern standard time on November 3, 2006.

Dated: October 27, 2006

By the direction of Mary Ellen Bittner Administrative Law Judge

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 27, 2006, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Jahie L. Stulin

Law Clerk to Mary Ellen Bittner Administrative Law Judge

> MCKMDL00496345 P-00016 00040

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### RULING ON REQUESTED EXTENSION

On October 27, 2006, counsel for Respondent filed a request for a second extension of time, to November 3, 2006, to file its prehearing statement in the above-captioned matter. Counsel for Respondent advised that counsel for the Government does not oppose the extension.

Inasmuch as it appears that no prejudice will result, Respondent's request is granted. Accordingly, Respondent may file its prehearing statement no later than 4:00 p.m. eastern standard time on November 3, 2006.

Dated: October 27, 2006

By the direction of Mary Ellen Bittner Administrative Law Judge

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 27, 2006, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

amie L. Stulin

Law Clerk to Mary Ellen Bittner Administrative Law Judge UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

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In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

### PREHEARING STATEMENT OF MCKESSON CORPORATION

John A. Gilbert, Jr. Hyman, Phelps & McNamara PC 700 Thirteenth Street, N.W. **Suite 1200** Washington, D.C. 20005 (202) 737-5600 (202) 737-9329 (Fax)

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## PREHEARING STATEMENT OF MCKESSON CORPORATION

McKesson Corporation ("McKesson") by and through the undersigned counsel, respectfully submits this prehearing statement pursuant to the Orders issued by this tribunal on September 11, 2006 and October 23, 2006.

#### I. ISSUE

1. Whether the Drug Enforcement Administration ("DEA") has demonstrated, by a preponderance of the evidence, that Respondent's DEA Certificate of Registration (#PM0000771) as a distributor of controlled substances at its Lakeland, Florida distribution center (DC) should be revoked as inconsistent with the public interest as that term is defined under 21 U.S.C. §§ 824(a) and 823(f).

#### II. PROPOSED STIPULATIONS OF FACT

Hydrocodone is a Schedule III controlled substance pursuant to
 C.F.R. § 1308.13(e).

# III. RESPONDENT'S WITNESSES AND SUMMARIES OF PROPOSED TESTIMONY

#### A. Witness List

William Mahoney
 Distribution Center Manager
 McKesson Corporation
 1515 West Bella Vista
 Lakeland, Florida 33805

- Colin Dilley
   Warehouse Supervisor
   McKesson Corporation
   Lakeland, Florida
- 3. Cassandra Wentworth
  Computer Room Supervisor
  McKesson Corporation
  Lakeland, Florida
- Debra Butcher
   DEA Diversion Investigator
   Tampa, Florida
- Kyle Wright
   DEA Diversion Investigator
   Washington, DC
- 6. Gary Hilliard
  Director of Regulatory Affairs
  McKesson Corporation
- 7. Ron Bone
  McKesson Corporation
  San Francisco, California
- Jake Kramer
   McKesson Distribution Center Manager
   McKesson Corporation
   Denver, Colorado
- Donald Walker
   Senior Vice President
   McKesson Corporation
   San Francisco, California

#### B. Summary of Proposed Testimony

#### 1. Proposed Testimony of William Mahoney

Mr. Mahoney will testify as to his background and educational experience and provide testimony about his responsibilities as the Distribution Center Manager (DCM) for the McKesson Lakeland DC. He will testify on the policies and procedures for handling controlled substances. Mr. Mahoney will testify that he has a BA in English from Dartmouth College and an MBA, specializing in Industrial Science, from Carnegie Mellon University. Mr. Mahoney has worked in sales, information technology and production management positions at IBM and Morton International. He has eight years experience in the wholesale drug distribution industry at Cardinal Health and McKesson.

#### a. Overview of the Lakeland Facility

Mr. Mahoney will testify about the general characteristics of McKesson's DCs and specifically about the business conducted at the Lakeland DC. [Ex. 1] He will testify that McKesson serves tens of thousands of customers nationwide. Sales of prescription drugs, including controlled substances to pharmacies vary greatly based on the size and type of customer. The Lakeland DC serves hospitals, health clinics, pharmacies and other health care entities. In particular, the size and other characteristics of pharmacies affect the type and amount of controlled substances purchased by a pharmacy. The Lakeland DC serves over 2,000 customers, and about 1,700 of these customers purchase controlled substances from the facility. The Lakeland DC distributes to customers nationwide but

primarily to customers in Florida, Georgia and Alabama. The average monthly sales of health care products for this facility exceeds \$250 million. About 15 percent of these sales involve controlled substances. Mr. Mahoney will testify that the Lakeland DC recently increased the number of customers that it serves because of requirements mandated by recent changes in federal and state drug pedigree laws. The drug pedigrees are required for all prescription drugs including controlled substances. The Lakeland DC is equipped with the necessary systems to accurately document and produce drug pedigree documentation for its customers.

Mr. Mahoney will testify as to the personnel responsible for compliance with federal and state regulations regarding controlled substances. Mr. Mahoney will describe the roles and responsibilities of employees who receive and handle controlled substances. He will testify that the Lakeland facility employs about 160 employees. Of these 20 employees are involved in the receipt, handling, security and distribution of controlled substances. Background checks and employee drug testing are conducted on all employees with access to controlled substances.

These employees are also provided training on policy and procedures for handling controlled substances, including state and DEA requirements. [Ex. 2] A written DEA Policies and Procedures Manual is made available to all employees to ensure compliance with these requirements.

The facility also employs a warehouse supervisor, who is responsible for all activities in the controlled substance vault and cage. Mr. Mahoney and the warehouse supervisor are responsible for all activities conducted with controlled

substances. [Ex. 3] Mr. Mahoney will testify that monthly meetings are conducted with all controlled substances staff to review procedures and discuss ways to improve procedures to ensure safe handling of controlled substances and compliance with state and federal requirements.

He will testify as to the physical security at the facility and the procedures followed to ensure security of controlled substances stored at the facility. On a monthly basis, the Lakeland DC processes thousands of transactions involving controlled substances, including the receipt, storage and distribution to customers. For example, looking at two month period from August 2006 to September 2006, the Lakeland DC averaged 85,155 invoiced lines of controlled substances and sales of over 264,000 pieces (i.e. bottles) of controlled substances per month. This compares to over 1.1 million invoiced lines for all health care products.

Mr. Mahoney will testify that he believes that the Lakeland DC has maintained a strong record of compliance with DEA and state requirements. Mr. Mahoney will testify that the Lakeland DC has not been previously cited by DEA for any compliance violations. The last audit DEA conducted was October 24, 2001. Agents Miguel Soler and Theresa Garnett audited five items and found zero discrepancies. [Ex. 4] No security, reporting or recordkeeping violations were noted. He will testify that this is significant given the volume of controlled substances handled by the facility.

Mr. Mahoney will testify that the Lakeland DC has voluntarily cooperated with DEA in prior investigations and has provided DEA with reports and information upon request numerous times since he took over the facility in 2001.

Mr. Mahoney will provide examples of McKesson's cooperation with DEA during this time which includes providing ad hoc reports to DEA upon request.

#### b. Verification of Customers

Mr. Mahoney will testify as to the procedures used by the Lakeland DC to establish new customer accounts and to verify that its customers are appropriately licensed. He will testify that customers are required to go through a thorough financial check before any new account is opened. [Ex. 5] The Lakeland DC employs five (5) sales representatives who handle independent accounts and seven (7) sales representatives who handle hospital and other types of health care entities. The sales representatives are trained to require that new customers submit the appropriate state and federal licenses before any shipments are made to new accounts. Mr. Mahoney will testify that this information is verified at the Lakeland DC and customers cannot receive controlled substances until the DC has verified that a current state and federal license are on file. A tickler file is maintained to track expiration dates.

## c. Recordkeeping and Reporting Systems

Mr. Mahoney will testify that the Lakeland DC employs two (2) individuals to handle electronic recordkeeping and reporting requirements. These individuals, Cassandra Wentworth and Adam Voytek, are responsible for generating ARCOS

reports and maintaining other data required by DEA regulations. Mr. Mahoney will testify that the Lakeland DC has recently improved these systems and increased focus on accuracy of the ARCOS and other DEA recordkeeping and reporting systems. He will discuss the reports generated on a daily, monthly and quarterly basis (e.g., the "DU 45" report) that enable the Lakeland facility to monitor sales of controlled substances. [Ex. 6] He will discuss the improved procedures for review of controlled substance exception reports.

Mr. Mahoney will discuss the policies and procedures used by the Lakeland DC to file reports of higher than average volume for controlled substances. There reports are generally labeled as "suspicious order" reports. Mr. Mahoney will testify as to his understanding of the basis for these reports. He will also testify as to the distinction between reports involving higher than average volumes and reports or investigations where the Lakeland DC has specific concerns about a customer or order involving controlled substances. He will discuss the criteria for the reports established based on information provided by DEA on historical averages of purchases by customers. Mr. Mahoney will testify about prior reports submitted to DEA about customers that have purchased in excess of historical averages. Mr. Mahoney will testify as to DEA's response to these reports.

Mr. Mahoney will testify about the Lakeland DC's relationship with DEA and voluntary cooperation with DEA in prior investigations. He will testify as to his prior response to subpoenas issued by DEA. He will testify that the Lakeland

DC has provided reports to DEA on an ad hoc basis without requiring a subpoena or notice of inspection.

He will discuss procedures that Lakeland DC uses to follow-up with customers on potential suspicious orders. For example, the Lakeland DC received a notice from McKesson's Director of Regulatory Affairs that DEA had identified Direct Pharmacy as an Internet pharmacy. The pharmacy was required to complete an Internet questionnaire. [Ex. 7] The Lakeland DC immediately terminated sale of any controlled substances to this facility until it completed its investigation. He will testify that Direct Pharmacy called the Lakeland DC and requested a meeting to show that the pharmacy was conducting a legitimate business. The Lakeland DC also received a telephone call from the Orlando DEA Field Office asking why the Lakeland DC had stopped selling to Direct Pharmacy. The Lakeland DC explained to the DEA Orland office that this action was based on information received from DEA headquarters. Employees from the Lakeland DC (Brian Westmoreland and Heather Harris) visited Direct Pharmacy in June 2006. Based on this visits and the notice received from DEA, McKesson decided not to reopen the account for controlled substances.

#### d. Distribution Procedures in Case of Emergencies

Mr. Mahoney will testify that because of its location the Lakeland DC is often required to take extraordinary measures to ensure that customers receive an uninterrupted supply of medicines, including controlled substances. This includes authorizing customers to purchase larger amounts of drugs than normal in

anticipation of storms as happened when Hurricane Katrina devastated Florida and the gulf states on August 25, 2005 and Hurricane Rita caused extensive damage in Florida on September 20, 2005. The most relevant example was on October 19, 2005, when the Lakeland DC received reports from the National Hurricane Center that Hurricane Wilma was due to hit over the weekend and could be a category 5 strength storm. The Lakeland DC called customers, urging them to order heavily in preparation for the event that it might not be able to reach them on Monday and for sometime thereafter.

#### e. Hydrocodone Sales

Mr. Mahoney will discuss the sales of hydrocodone products to customers. He will testify that the DC has over 100 customers that purchase hydrocodone products most of which are pharmacies. [Ex. 8] Mr. Mahoney will testify that sales of hydrocodone-containing drugs (including Norco and Vicodin) represent less than a half percent (.5%) total sales of prescription drugs for the facility. He will testify as to the amounts purchased by many of these customers and the frequency of such purchases. [Ex. 9]

Mr. Mahoney will testify as to the due diligence completed for each of the seven pharmacies identified in DEA's order to show cause: Accumed, Avee, Bi-Wise, Medipharm, Trelles, United prescription Services and Universal RX. He will testify that the Lakeland DC documented that each of the pharmacies maintained at all relevant times the appropriate state, federal and DEA registrations as retail pharmacies. He will testify as to the responses received from

each pharmacy from the Internet questionnaires sent to these pharmacies on dispensing of controlled substances.

Mr. Mahoney will testify the Lakeland DC opened the Accumed account on May 25, 2005. He will testify as to the steps used to verify this account. [Ex. 10] He will discuss the controlled substances purchased by this facility. [Ex. 11-13] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex. 14]

Mr. Mahoney will testify the Lakeland DC opened the Avee

Pharmaceutical account on February 2, 2004. He will testify as to the steps used to verify this account. [Ex. 15] He will discuss the controlled substances purchased by this facility. [Ex. 16-18] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex.19]

Mr. Mahoney will testify the Lakeland DC opened the Bi-Wise Pharmacy account on in January 2003. He will testify as to the steps used to verify this account. [Ex. 20] He will discuss the controlled substances purchased by this facility. [Ex. 21-23] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex. 24]

Mr. Mahoney will testify the Lakeland DC opened the MediPharm account in October 2005. He will testify as to the steps used to verify this account. [Ex. 25] He will discuss the controlled substances purchased by this facility. [Ex. 26-28] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex.29]

Mr. Mahoney will testify the Lakeland DC opened the Trelles Pharmacy account in February 2006. He will testify as to the steps used to verify this account. [Ex. 30] He will discuss the controlled substances purchased by this facility. [Ex. 31-33] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex.34]

Mr. Mahoney will testify the Lakeland DC opened the United Prescription Services account in July 2004. He will testify as to the steps used to verify this account. [Ex. 35] He will discuss the controlled substances purchased by this facility. [Ex. 36-38] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex.39]

Mr. Mahoney will testify the Lakeland DC opened the Universal Rx account in October 2005. He will testify as to the steps used to verify this account. [Ex. 40] He will discuss the controlled substances purchased by this facility. [Ex. 41-43] He will also testify as to the information received from this account in response to the Internet questionnaire. [Ex. 44]

Mr. Mahoney will testify that on October 3, 2005, the Lakeland facility received a telephone call from DEA Diversion Investigator (DI) Debra Butcher of DEA Tampa Field Office. Ms. Butcher informed Mr. Mahoney that a potential customer, Lexus Pharmacy, is a "suspicious" pharmacy and that the Lakeland DC needs to follow procedures for ensuring that it is not distributing products in violation of the law and regulations. Ms. Butcher requested that the Lakeland DC notify Ms. Butcher as to the action that the Lakeland DC intends to take. Ms.

Butcher stated that she expected that these telephone calls would become a regular part of the interaction between DEA and the Lakeland DC. Mr. Mahoney will testify that McKesson declined to open Lexus Pharmacy as a customer based on this conversation. He will also testify that Ms. Butcher later notified the Lakeland DC that Lexus had agreed to stop the "offensive behavior," and that DEA had no objections to Lakeland DC doing business with them. McKesson declined to open the account.

Mr. Mahoney will also testify that on November 21, 2005, DI Butcher contacted the Lakeland DC and requested an Internet checklist for Avee Pharmacy. He will testify that she contacted the Lakeland DC again on November 22, 2005 to request a progress report. At that time Ms. Butcher stated that she had inspected the Avee facility and found its business to be "questionable." Mr. Mahoney will testify that he notified McKesson management about this issue immediately.

Mr. Mahoney will testify that on November 22, 2005, as a result of a decision made by Donald Walker, Senior Vice President of Distribution

Operations, the Lakeland DC dramatically reduced sales to six pharmacies. Mr.

Mahoney will testify that he was aware that DEA had provided the names of the six pharmacies to McKesson as "pharmacies of concern" through outside counsel. Initially these pharmacies were reduced to only 300 dosage units of hydrocodone per day. Mr. Mahoney will further testify as to the steps taken to monitor future sales to these pharmacies on a daily basis. He will testify as to internal procedures

employed by the Lakeland DC to monitor drug strength and quantity. Mr.

Mahoney will testify that the Lakeland DC had not received any prior information that any of these pharmacies were involved in unlawful dispensing of controlled substances.

Mr. Mahoney will testify that on November 28, 2005, he contacted DI Butcher by telephone to collaborate with DEA on its need for information on excessive purchases (that is, the "DU-45" report) and determine what information DEA needed about certain customers. Mr. Mahoney will testify that Ms. Butcher was unclear as to the exact amount of controlled substance orders that would indicate an issue regarding dispensing of controlled substances. However, she stated that DEA was not generally interested in reports about hospitals, large mail order, or chains—only independents, and perhaps some closed-door pharmacies. She stated that in regard to possible unlawful dispensing: "we know it when we see it."

Mr. Mahoney will testify that on November 29, 2005 he began to receive complaints from all of the pharmacies whose orders had been significantly reduced. He will testify that he called DI Butcher to discuss the confusion and complaints coming from customers over the limited quantities, however, DI Butcher did not return his telephone call. [Ex. 45]

Mr. Mahoney will also testify that on November 29, 2005, the Lakeland DC received a report from Pete Pardo, a senior sales representative about some of the pharmacies in question. Pete Pardo had conducted a due diligence audit at five

of the six pharmacies where the Lakeland DC had reduced sales of hydrocodone. Mr. Pardo had used the Internet questionnaire developed by McKesson as well as additional questions provided by McKesson about its business. Based on these responses, Mr. Walker agreed to increase the daily sales to these customers to 2,000 dosage units. This amount was still significantly lower than the prior purchases by these pharmacies.

Mr. Mahoney will also testify that on November 29, 2005 at about 3:15pm, he called DI Butcher and informed her that the Lakeland DC was limiting quantities to the six pharmacies but raising the limit to 2000 units per day. [Ex. 46] Mr. Mahoney will testify that Ms. Butcher stated that Michael Mapes was the best source of information on "levels and limits." Mr. Mahoney will also testify that she told him that how much the Lakeland DC was selling "is our business."

Mr. Mahoney will testify that after November 28, 2005 he continued to receive telephone calls from the six affected pharmacies and many claimed that they had been inspected by DEA and been cleared. Mr. Mahoney will testify that he did not take their word for it but instead on December 8, 2005 contacted DI Butcher to confirm their statements. [Ex. 47] DI Butcher told Mr. Mahoney that DEA had inspected some of these pharmacies but DEA did not give them an all clear. Mr. Mahoney will testify that the Lakeland DC kept these sales restrictions in place.

Mr. Mahoney will testify that in early December 2005, the Lakeland DC provided additional guidance to its sales representatives including a list of

customers with high purchases. [Ex. 48] He will testify that the sales staff were instructed to review all of these accounts. He will also testify that on December 21, 2005, additional notices were sent to sales staff regarding high volume accounts. [Ex. 49] A revised questionnaire to be used with new accounts was provided to sales staff.

Mr. Mahoney will testify about information he received that the accounts that McKesson had reduced were receiving products from other distributors. For example, on December 22, 2005, he was contacted by representatives of Accumed Pharmacy. These representatives provided a copy of an invoice showing that Accumed had received 30,000 dosage units in one order from Direct Dispensing of Miami. Accumed asked why McKesson could not supply the same amount as other distributors. The Lakeland DC still declined to increase sales to Accumed.

Mr. Mahoney will testify that Lakeland has implemented new procedures for monitoring pharmacy accounts and is taking all steps necessary to ensure that its pharmacy accounts are engaged in legitimate dispensing.

#### 2. Proposed Testimony of Colin Dilley

Mr. Dilley will testify as to his background and experience as the Warehouse Supervisor at the Lakeland DC. Mr. Dilley will testify as to the policies and procedures implemented by McKesson to maintain security at the Lakeland DC regarding controlled substances. [Ex. 50] He will also testify as to

the procedures for protecting against diversion at the facility including review of current and new customer accounts.

#### 3. Proposed Testimony of Cassandra Wentworth

Ms. Wentworth will testify as to her background and experience as the Computer Room Supervisor at the Lakeland DC. She will testify as to the recordkeeping and reporting systems that McKesson has implemented to track controlled substances. Ms. Wentworth will testify as to the "suspicious order" reports filed with DEA on a routine basis. [Ex. 51] She will testify that the Lakeland DC routinely submitted suspicious order reports to DEA at least once per month. She will testify that the Lakeland DC submitted a suspicious order report to DEA on October 19, 2005 identifying Avee Pharmacy as having purchased an extraordinary amount of controlled substances and again on November 10, 2005 for Accumed and Avee Pharmacy. [Ex. 52 and 53]

Ms. Wentworth will testify as to the improvements and new procedures used to generate these reports as well as improvements to the ARCOS reporting system and daily excessive order reports.

#### 4. Proposed Testimony of Debra Butcher

Diversion Investigator (DI) Butcher is expected to testify as to the conversations that she had with the Lakeland DC on questions about pharmacies in the Tampa area that may be dispensing controlled substances via the Internet. She is expected to testify about the discussion she had with the Lakeland DC about

Avee and that she had not had a discussion with the Lakeland DC about United Prescription Services prior to November 28, 2006. She is also expected to testify about the investigations that she conducted at several Internet pharmacies in the Tampa area and the results of her investigation. DI Butcher is also expected to testify about her conversations with the staff at DEA Washington Headquarters, including Michael Mapes and Kyle Wright, about the Lakeland DC and Tampa area pharmacies.

#### 5. Proposed testimony of Kyle Wright

Diversion Investigator Kyle Wright is expected to testify as to the meeting he had with Avee Pharmacy about its pharmacy business. Mr. Wright is also expected to testify as to the information provide by Avee about the nature of the hydrocodone prescriptions received and the scope of its pharmacy practice. Mr. Wright is also expected to testify about meetings or conversations he has had with other pharmacies in the Tampa area.

#### 6. Proposed Testimony of Gary Hilliard

Mr. Hilliard will testify as to his background and experience in law enforcement and federal and state compliance issues in working with McKesson Corporation. Mr. Hilliard received a BS in biology from the University of Texas and is a certified hazardous materials manager. For the last nine years Mr. Hilliard has been the Director of Regulatory Affairs for McKesson Corporation. He is responsible for regulatory compliance for 35 DEA registered DCs. He provides

support to the DCs on all federal regulatory requirements and state requirements including boards of pharmacy and departments of health. Prior to working at McKesson, Mr. Hilliard had similar responsibilities for FoxMeyer Drug Company.

Mr. Hilliard will describe his roles and responsibilities at McKesson as the Director of Regulatory Affairs.

#### a. McKesson DEA Compliance Program

Mr. Hilliard will testify that McKesson is fully committed to working with DEA to maintain compliance at all of its DEA registered facilities. McKesson operates 35 DEA registered DCs nationwide that handle controlled substances. McKesson has a long track record of leading the industry in compliance on DEA regulations. Mr. Hilliard will testify that DEA compliance is part of the performance standards for McKesson's associates, well documented in McKesson's standard operating procedures (SOPs). These are internally audited annually. McKesson recognizes its responsibility to ensure that controlled substances are secure in the supply chain. McKesson has collaborated with DEA both at the headquarter and field levels on such projects as the suspicious orders task force, the development and implementation of controlled substance ordering system (CSOS), and devising a reporting system for fentanyl and Palladone.

Mr. Hilliard will also testify that McKesson has been aware of the improper practices of Internet pharmacies and prior to September 2005, has worked with DEA to resolve issues regarding potential excessive purchases by its pharmacy customers, particularly in California and Colorado. Mr. Hilliard will testify that

identifying and investigating Internet pharmacies poses unique problems for McKesson and all distributors, especially in cases where these pharmacies are registered with the state and DEA. He will testify that these pharmacies are often able to provide information on procedures used to verify practitioner's licenses. Mr. Hilliard will testify that McKesson serves tens of thousands of customers nationwide and sales of controlled substances and other drugs to these customers varies greatly based on the size of the pharmacy and other characteristics of the pharmacy's specific practice.

#### b. Suspicious Orders

Mr. Hilliard will testify as to McKesson's participation in the DEA

Suspicious Orders Task Force (SOTF). He will testify that the SOTF was created in cooperation with DEA in the mid to late 1990's. [Ex. 54] McKesson participated in that task force to develop system parameters for screening suspicious orders. The Task Force established a calculation that involves a twelve (12) month rolling average of sales based on an item number. Mr. Hilliard will testify that the industry and DEA agreed on a variation factor to allow for seasonal fluctuations. The threshold criteria established for suspicious orders involved a factor of three (3) times the average for CII drugs and a factor of eight (8) times average for III-V drugs and List I products.

Mr. Hilliard will testify that McKesson implemented a suspicious order reporting system across all of its DCs. The report automatically generates every

night. [Ex. 55] The industry agreed to send immediately to DEA a report of any pharmacy that exceeded these values by fax. Mr. Hilliard will testify that large volumes of pharmacies were exceeding these values resulting in McKesson and other distributors faxing long reports to DEA on a nightly basis. DEA's fax machines were being inundated and DEA offices across the country notified the DCs to stop immediately. Mr. Hilliard will testify that DEA requested that the offices stated to send the report only if something is suspicious.

McKesson thereafter devised a system to require a person at each DC to review the reports to determine if the quantities are suspicious. If so, they are to fax the appropriate pages to DEA. The complete month end report is printed and mailed to DEA following each month.

Mr. Hilliard will also testify that a Customer Recap Report is also generated at month end and submitted to DEA. [Ex. 55] This report summarizes the monthly purchases by DEA ingredient base code. This provides a bigger picture by capturing the ingredient purchased regardless of the McKesson item number.

#### c. Compliance Programs for Internet Pharmacies

Mr. Hilliard will testify as to McKesson's ongoing efforts to investigate Internet pharmacies. Mr. Hilliard will testify that on October 31, 2005, he sent written Internet pharmacy guidelines to field personnel at all the DCs.

Mr. Hilliard will testify as to other examples of McKesson's efforts in this area. For example, in January 2005, the McKesson distribution center in Southern

California reported potential suspicious orders from a long time pharmacy customer to DEA. McKesson was concerned because the customer, Fallbrook Pharmacy had made several large purchases. DEA later informed McKesson that they had inspected Fallbrook and had no findings. Nevertheless, McKesson made a decision on January 18, 2005 to stop sales of controlled substances to Fallbrook.

#### d. Meeting with DEA on Internet Pharmacies

Mr. Hilliard will testify that on June 14, 2005, he was approached by Kyle Wright at the HDMA Conference in Florida to determine if McKesson and industry partners would be willing to participate in a meeting to work in conjunction with DEA to fight against illegal Internet activity. He will testify that he agreed to work with DEA but recommended that the best forum may be HDMA's Regulatory Affairs Committee.

Mr. Hilliard will also testify that on July 27, 2005, he was contacted by telephone by Michael Mapes and asked whether McKesson would agree to attend a meeting on Internet pharmacies. Mr. Hilliard agreed to assist DEA in these efforts.

Mr. Hilliard will testify that on September 1, 2005, he, along with Ron
Bone, and outside counsel, John Gilbert, attended a meeting with DEA in
Washington DC. The meeting was attended by Mike Mapes, Kyle Wright and Jim
Crawford. He will testify that a binder was provided to McKesson which included
a PowerPoint presentation, several court cases, DEA Internet policy, and a
questionnaire. DEA outlined the issue of Internet pharmacy abuse and provided

its views of appropriate Internet pharmacy businesses, and the distributor's responsibility to monitor and report suspicious orders. [Ex. 57] Mr. Hilliard will testify that he was surprised by the level at which DEA believed that distributors would have to be accountable to determine the nature of prescriptions dispensed by pharmacies. He will testify that in his opinion this standard was inconsistent with how the wholesale distribution industry had previously reviewed pharmacy accounts. In particular, he will testify that he is unaware of cases where wholesale distributors will routinely conduct audits of pharmacy accounts.

He will testify that DEA stated that Internet pharmacies in Colorado, Texas and Florida were of particular concern. Mr. Hilliard will also testify that DEA provided two handouts showing the excessive sales of hydrocodone by CityView Pharmacy in Colorado and Brighton Pharmacy in Colorado. [Ex. 58] The two pharmacies were part of a Rxplus buying group in Colorado. Mr. Hilliard will testify that McKesson outlined its suspicious ordering process and reports. DEA questioned whether these current reports were sufficient to capture the required information. DEA stated that they expected the Internet DEA questionnaire to be used as a guide by McKesson and other distributors.

e. Actions taken by McKesson in response to the DEA meeting and notices

Mr. Hilliard will testify as to the voluntary steps taken by McKesson in response to information received from DEA about potential issues with Internet pharmacies. Mr. Hilliard will testify that given DEA's focus on Colorado

pharmacies at the September meeting, McKesson immediately began an investigation into the pharmacies identified by DEA. Also, on September 7, 2005, the DEA Denver Field Office request sales data for Clear Springs Foothills Pharmacy.

Mr. Hilliard will testify that on September 8, 2005, Mr. Hilliard discussed the Internet pharmacy problem with Denver DCM Jack Kramer. This discussion included a discussion about CityView and Brighton Pharmacy. A follow-up phone call was held with McKesson employees on September 9, 2005. On September 11, 2005, Mr. Hilliard sent a copy of the questions provided by DEA to the Denver DC to be used with new accounts. On September 22, 2005, McKesson received news reports on DEA's suspension of Lindy's and CityView Pharmacy's registration in Denver, Colorado. All controlled substance sales to these two accounts were immediately terminated.

Mr. Hilliard will also testify that on September 27, 2005, McKesson received an e-mail from Kyle Wright and Mike Mapes on the suspension of the DEA registration for Crown Point Pharmacy and Sky Ridge Pharmacy. Both were located in Denver, Colorado. Mr. Hilliard immediately notified Jake Kramer, of the Denver DC. All controls were halted to this account.

Mr. Hilliard will testify that McKesson did not immediately focus on Florida pharmacies after the September 1, 2005 meeting because it appeared from the data provided to McKesson that Colorado was the immediate problem.

However, McKesson did initiate a program to develop a computer system to run

reports of hydrocodone sales in other parts of the country, including Florida, to determine if there were any problems in any other states. [Ex. 59]

Mr. Hilliard will testify that McKesson restricted sales to six pharmacies in Florida on November 28, 2006. He was aware that McKesson notified Michael Mapes of DEA through outside counsel that McKesson had restricted orders to six pharmacies: Accumed, Avee, Bi-Wise, Medipharm-Rx, United, and Universal Rx. Mr. Hilliard will testify that within a few days he received an e-mail from DEA that had been sent to all major distributors noting that a Florida distributor had restricted sales to Accumed, Avee, Bi-wise, Medipharm-Rx, United, and Universal Rx.

Mr. Hilliard will also testify that he was made aware that McKesson received letters from outside counsel for some of the six pharmacies threatening legal action if McKesson did fill orders for controlled substances.

Mr. Hilliard will testify that McKesson continues to cooperate with DEA on compliance issues and has acted aggressively when it has received information from DEA about Internet pharmacies. Mr. Hilliard will testify that such information is transmitted to all DCs. The DCs are requested to review their customer's lists and take appropriate action if a suspect company is identified. For example:

On August 22, 2005, McKesson received an e-mail stating a
distributor has stopped selling to some pharmacies in TX and FL. No
specific pharmacies were named. This alert was sent out to all DCs.

- On August 26, 2005, McKesson received an e-mail about the suspension of two Florida DEA registrations: Americare Health
   Solutions and Trinity Health Care. McKesson determined it did not serve these pharmacies.
- On December 12, 2005, the Conroe, TX DC notes high orders for several accounts including Aspen Pharmacy. Mr. Hilliard spoke with the DCM, Jon Cox, regarding the necessary due diligence and DEA's expectations. Sales managers are to utilize questionnaire with selected accounts.
- On February 16, 2006, Lakeland performed Internet survey on a pharmacy called: "Save on Rx." As a result of the audit the Lakeland DC stopped filling controlled substance orders.
- On March 7, 2006, the Lakeland DC terminated delivery of controls to Pharmacy One Pro Specialty and Direct Pharmacy, after receiving notification from DEA.
- On March 8, 2006, the Landover DC reported Newcare Pharmacy to DEA for suspicious orders. DEA stated they are working on this pharmacy.
- On April 12, 2006, Mr. Mapes sent an e-mail to McKesson about CRJ Pharmacy, Florida. CRJ had applied to do business with McKesson but the account was rejected.

 In March 2006, the McKesson Omaha DC, using the Internet questionnaire, temporarily stopped selling to a local pharmacy,
 Walker Pharmacy.

Mr. Hilliard will also testify as to McKesson's investigation into allegations by DEA of erroneous DEA registration numbers contained in ARCOS reports submitted to DEA.

#### 7. Proposed Testimony of Ron Bone

Ron Bone will testify as to his background and experience and his position as a vice president at McKesson Corporation. Mr. Bone will testify as to his responsibilities at McKesson Corporation and the functions of his office.

Mr. Bone will testify as to the actions taken by McKesson following the meeting with DEA on September 1, 2006. In addition to Mr. Hilliard's testimony, Mr. Bone will state that he also noted at that meeting that DEA mentioned a Florida pharmacy, United Prescription Services, as a pharmacy that DEA had some concerns about. However, DEA did not provide any printouts for this pharmacy and he will testify that he did not consider this pharmacy a priority.

Mr. Bone will testify about McKesson's investigation into the two
Colorado pharmacies identified by DEA as receiving large quantities of
hydrocodone. He will testify as to discussions with DEA's Denver Field Office
and the DCM at McKesson's Denver DC.

Mr. Bone will testify that beginning October 3, 2005, he instructed Sharon Mackarness to begin working on creating sales reports based on DEA criteria. He will testify that McKesson ran reports for several regions around the country including Florida, Texas and Colorado. [Ex. 60 and 61] He will also testify that these report regions were later expanded to include the Northeast region. In some cases, data from the reports were used to perform additional due diligence investigations. For example, the first extraction of sales data indicated that several customers in the Memphis, Tennessee area showed purchases that were higher than the average volume. Based on a follow-up review it was determined that these pharmacies were not involved in the Internet pharmacy business.

Mr. Bone will testify that as a result of the information provided by DEA on November 22, 2005, McKesson reviewed the reports that had been generated in September and October 2005 on all of the Lakeland DC accounts. He will testify that it was determined that the report failed to pick up all of the generics of hydrocodone and thus understated the number of purchases being made by these accounts.

#### 8. Testimony of Jake Kramer

Mr. Kramer will testify as to his background and experience as the DCM at McKesson's Denver DC. He will testify about his discussions with the Denver DEA office in September and October of 2005 about Brighton Pharmacy and CityView Pharmacy. He will also testify as to the actions taken by the Denver DC

as a result of these discussions. He will testify that on October 7, 2005, the

Denver DC reported a suspicious order from Foothills Pharmacy to the Denver

DEA Field Office. [Ex. 62] DEA requested in writing the report of suspicious

order, form of monitoring, and copies of daily purchases. He will testify that the

Denver DC stopped sales of controlled substances to this customer until the issue

was resolved.

Mr. Kramer will also testify that Brighton Pharmacy became an issue again for the Denver DC in the spring of 2006 because of the fact that Brighton Pharmacy and another pharmacy, Western Pharmacy, were owned by the same individual. He will testify that Denver DC discontinued doing business with Western States after receiving information from DEA that they were dispensing prescriptions via the Internet. He will testify that on February 13, 2006, the Colorado Board of Pharmacy requested information about distributions to Western Pharmacy. [Ex. 63] On March 2, 2006, the Denver DEA interviewed employees of the McKesson Denver DC. He will testify that he informed DEA that McKesson had stopped selling controls to Brighton and Western States.

Mr. Kramer will testify that he learned on April 5, 2006, that Western States' DEA registration was reissued. He will testify that on April 10, 2006, Brighton Pharmacy attempted to order controls for Western State Pharmacy. The Denver DC's audit system flagged this order and it was cancelled. He will testify that this information was provided to DEA.

Mr. Kramer will also testify that he was informed on April 18, 2006 that Brighton Pharmacy and Western Pharmacy threatened to open an account with another major wholesaler, costing McKesson a 20 year account for controlled substances. McKesson continued to work with the Denver DEA office and did not re-open the account because DEA could not provide any information that the issues had been clarified. He will testify as to his knowledge of the current status of the DEA registrations for Brighton and Western Pharmacy.

#### 9. Proposed Testimony of Donald Walker

Mr. Walker will testify as to his education and background. Mr. Walker will testify that he is the Senior Vice President for Distribution Operations. Mr. Walker has 26 years of experience the wholesale distribution industry and nine years of experience in law enforcement. Mr. Walker has a BS in Zoology from the University of California and master's degree in Public Administration from Golden Gate University. Mr. Walker will testify as to his responsibilities at McKesson Corporation.

Mr. Walker will testify that McKesson has led the industry in the delivery of medicines and healthcare products to pharmacies, hospitals and other healthcare entities for over 173 years. A Fortune 16 corporation, McKesson delivers vital pharmaceuticals, medical supplies and health information technology solutions that touch the lives of more than 100 million patients in every healthcare setting. McKesson purchases pharmaceutical products from more than 450 manufacturers

and supplies over 75,000 customer sites across America. Each week, McKesson delivers over \$1 billion worth of pharmaceuticals, or one-third of all medicines used in North America, to healthcare providers in every state. Consequently, McKesson understands the critical importance of medication safety and the need to protect the integrity of the pharmaceutical distribution network. As the largest pharmaceutical distributor in North America, McKesson has an unwavering commitment to the safe, efficient and cost-effective distribution of pharmaceutical products

Mr. Walker will testify that he was initially notified about DEA concern about Internet pharmacies after the meeting with DEA on September 1, 2006. He will testify that McKesson management took DEA's concern very seriously. Additionally, discussions on the appropriate next steps were reviewed and included running regional sales reports based on the criteria provided by DEA. At the September meeting, DEA identified several Colorado pharmacies by name. Upon notification that DEA had suspended the registrations of these pharmacies, McKesson immediately terminated the authority for these Colorado pharmacies to order controlled substances from McKesson.

McKesson has also distributed educational information on Internet
pharmacies to Operations and Sales personnel. The materials included DEA's
expectations, a checklist questionnaire, and data received during the September 1st
meeting at DEA Headquarters. Using the DEA questionnaire, sales personnel for

all of the McKesson distribution centers reviewed their customers to determine if those customers were operating over the Internet.

Mr. Walker will testify that he was notified on November 21, 2006 by outside counsel that DEA was extremely concerned about excessive distribution of hydrocodone products to six specific pharmacies in the Tampa, Florida area. He will testify that based on the information provided by DEA he made an immediate decision to significantly reduce sales to these customers. Although McKesson did not have any information at the time that these pharmacies were not engaged in the legitimate distribution of drugs, he decided that McKesson should immediately investigate the matter to determine whether there were any problems with these customers.

He will testify that McKesson immediately imposed a limitation on all of these pharmacies and cut sales of hydrocodone to these pharmacies to only ten (10) percent of the prior orders. Mr. Walker will discuss this process and the additional adjustments made to these accounts. Mr. Walker will testify that McKesson received several complaints by counsel for these customers as a result of this action. McKesson also began an investigation of all of these pharmacies which included requesting additional information from the pharmacies about their customers and steps taken to verify that prescriptions filled are legitimate.

Mr. Walker will also testify that he sought a meeting with DEA as soon as possible to discuss the problem. Mr. Walker will testify that he attended a meeting

with DEA on January 6, 2006 to discuss DEA's concerns. He will testify that DEA expressed concerns about the amount of hydrocodone sold in a relatively short period to several pharmacies in Florida. Mr. Walker will testify that he assured DEA that McKesson would take appropriate steps to reduce distribution to Internet pharmacies. Mr. Walker agreed to provide DEA with a full report of all distributions of hydrocodone to the six pharmacies for the October – December time period.

Immediately after McKesson's January 2006 meeting with DEA,

McKesson discontinued sales of all controlled substances to these six pharmacies.

Mr. Walker will also testify that McKesson took additional steps to improve its

compliance program. For example, on January 10, 2006, the McKesson IT

department created a "vicodin" report to assist the DC's in monitoring excessive

orders. Also in February 2006, a new suspicious monitoring report was created.

[Ex. 64]

Mr. Walker will testify about the steps that McKesson has taken to reduce the potential for excessive purchases of controlled substances at all of its facilities, including the Lakeland DC.

Mr. Walker will testify that the company has distributed educational information on Internet pharmacies to all of its Operations and Sales personnel.

The materials include a briefing on the problem of Internet pharmacies based on

the material distributed by DEA headquarters and a customer checklist and questionnaire to be used with existing and new accounts.

Mr. Walker will also testify that using the Internet questionnaire previously issued by DEA, sales personnel for all of the McKesson distribution centers have been required to review their customers to determine if those customers were operating over the Internet. All such accounts will be immediately investigated and subject to suspension and/or termination should prescriptions not be distributed for a legitimate medical purpose.

Mr. Walker will also testify that McKesson's Regulatory Affairs group will review new pharmacy accounts to ensure that the amount and type of controlled substances purchased are consistent with legitimate pharmacy practice. All DCMs will be required to request review by McKesson's Regulatory Affairs section on new accounts that place orders for controlled substances.

Mr. Walker will testify that McKesson is reviewing a policy to establish a monthly threshold for dosage forms of hydrocodone for all pharmacy customers at each of its facilities. Customers requesting to purchase more than this amount will be required to provide additional information on its dispensing practices to justify amounts above this threshold. Such information will be reviewed by McKesson Regulatory Affairs section before a customer will be authorized to purchase more than the threshold per month. McKesson will also establish thresholds for other

controlled substances purchases. He will also testify that each McKesson DC will submit a list each quarter to the local DEA office to include any customer who places an order for hydrocodone that exceeds the threshold dosage units per month.

Mr. Walker will testify that McKesson is prepared to provide financial and other resources to assist DEA in developing an industry-wide database to educate manufacturers and distributors about issues involving Internet and mail order sales. The objective would be to pool the resources of government and industry to facilitate the collection and dissemination of information about potential violations and improper practices by individuals and entities involved in dispensing controlled substances.

Mr. Walker will testify that McKesson's long track record with DEA indicates that its continued registration in Lakeland and at all its DCs is in the public interest. Revocation of the Lakeland facility will serve no just purpose and could significantly harm the delivery of important medicines to a large population.

### IV. RESPONDENT'S PROPOSED DOCUMENTARY EXHIBITS

The Respondent proposes to introduce the following documents.

Respondent may request to supplement these documents at a later date.

- 1. Photographs of Lakeland DC.
- 2. Copy of excerpts from Lakeland DC policies and procedures regarding the handling of controlled substances
- 3. Photographs of Controlled Substances Security Cage
- 4. McKesson Report of Contact with the DEA, October 2001

- 5. Copy of relevant customer forms
- 6. Copy of Sample DU-45 Report
- Copy of completed Internet Pharmacy questionnaire from Direct Pharmacy
- Spreadsheet depicting Lakeland DC customers purchasing hydrocodone for 2005 and 2006
- 9. Spreadsheet on 2005 and 2006 pharmacy sales of hydrocodone
- 10. Copy of Florida state pharmacy license for Accumed
- 11. Copy of response to Internet questionnaire from Accumed
- 12. Copy of DEA registration for Accumed
- 13. Copy of spreadsheet depicting 2005 sales of controlled substances to Accumed
- 14. Copy of Lakeland DC customer file for Accumed
- 15. Copy of Florida state pharmacy license for Avee Pharmacy
- 16. Copy of DEA Registration for Avee Pharmacy
- 17. Copy of Lakeland customer file for Avee Pharmacy
- 18. Copy of Internet questionnaire from Avee
- 19. Copy of Avee spreadsheet depicting 2005 sales of controlled substances
- 20. Copy of Florida state license for Bi-Wise Pharmacy
- 21. Copy of DEA registration for Bi-Wise Pharmacy
- 22. Copy of Lakeland DC customer file for Bi-Wise Pharmacy
- 23. Copy of response of Internet questionnaire by Bi-Wise
- Copy of spreadsheet depicting 2005 sales of controlled substances to Bi-Wise
- 25. Copy of Florida Pharmacy License for Medipharm
- 26. Copy of DEA registration for Medipharm
- 27. Copy of Lakeland DC customer file for Medipharm
- 28. Copy of response to Internet questionnaire by Medipharm
- 29. Copy of spreadsheet depicting 2005 sales of controlled substances to Medipharm
- 30. Copy of Florida state pharmacy license for Trellis Pharmacy
- 31. Copy of DEA registration for Trellis Pharmacy
- 32. Copy of Lakeland DC customer file for Trellis Pharmacy
- 33. Copy of response to Internet pharmacy questionnaire by Trellis Pharmacy
- 34. Copy of spreadsheet depicting 2005 sales of controlled substances to Trellis Pharmacy
- 35. Copy of Florida state pharmacy license for United Prescription Services
- 36. Copy of DEA registration for United Prescription Services
- 37. Copy of Lakeland DC customer file for United Prescription Services
- 38. Copy of response to Internet questionnaire from United Prescription Services

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- 39. Copy of spreadsheet depicting 2005 sales of controlled substances to United Prescription Services
- 40. Copy of Florida state pharmacy license for Universal RX
- 41. Copy of DEA registration for Universal RX
- 42. Copy of Lakeland DC customer file for Universal RX
- 43. Copy of response to Internet questionnaire by Universal RX
- 44. Copy of spreadsheet depicting 2005 sales of controlled substances to Universal RX
- 45. Copy of DEA consultant audit for Universal RX
- 46. Report of Contact with DEA, November 29, 2005
- 47. Report of Contact with DEA, December 8, 2005
- 48. Notice to Sales representatives, December 2005
- 49. Copy of Internet questionnaire used by Lakeland DC
- 50. Security pictures of DEA cage.
- 51. Copies of suspicious order reports filed with DEA, multiple dates.
- 52. Copy of suspicious order reports for Avee Pharmacy and Accumed
- 53. Copy of suspicious order reports for Avee and Accumed
- 54. SOTF Report
- 55. DU-45 Report
- 56. Customer Recap Report
- 57. DEA Manual on Internet pharmacies
- 58. DEA printouts from September 1, 2205 meeting with McKesson
- 59. McKesson reports of hydrocodone sales in sales regions for 2005.
- 60. McKesson reports of controlled substance sales by region for 2005
- 61. McKesson reports of hydrocodone by region 2005.
- 62. Suspicious order report from Denver DC to Denver DEA office
- 63. Colorado Board of Pharmacy request to McKesson
- 64. Suspicious Order Report

### V. PROPOSED VENUE

Tampa, Florida

### VI. TIME FOR HEARING

Respondent expects its case to take approximately three days exclusive of cross examination.





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Date

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wayne Patrick Honorable Mary Ellen Bitther

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John Ollbert

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Wayne Patrick Honorable Mary Ellen Bitmer

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CHERYL F GRAHAM MD. FCP REGULATORY SCIENTIST

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JAMES S. PHELPS

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BRIAN J. DONATO

DIANE B. McCOLL

JOHN R. FLEDER

MARCH SHAPIRO

•••

John Gilbert

DATE:

November 3, 2006

TO:

FROM:

Honorable Mary Ellen Bittner

FAX NO.:

(202) 307-8198

Fax No.: (202) 737-9329

Wayne Patrick

(202) 307-4946

NO. OF PAGES (including this page):

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## UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

### PREHEARING RULING

On November 27, 2006, the undersigned conducted a prehearing conference by telephone with counsel for both parties. This Prehearing Ruling is made pursuant to 21 C.F.R. § 1316.55 (2006).

### I. ISSUE

Whether a preponderance of the evidence establishes that Respondent's Drug Enforcement Administration registration as a distributor at its Lakeland, Florida location should be revoked because its continued registration would be inconsistent with the public interest as that term is used in 21 U.S.C. §§ 824(a) and 823(b) and (e).

### II. STIPULATIONS

1. Hydrocodone is a Schedule III narcotic controlled substance pursuant to 21 C.F.R. § 1308.13(e).

### III. WITNESSES

Counsel for both parties intend to call the witnesses identified in their respective prehearing statements to testify as indicated therein. No later than 4 p.m. eastern standard time on March 19, 2007, both parties are to file supplemental prehearing statements, which shall indicate any additional witnesses who will testify and detail their testimony.

Counsel should note that I generally restrict cross-examination of witnesses to matters covered on direct examination; however, if a party submits an affidavit or letter into evidence from a witness who also testifies in person, I will permit cross-examination as to matters referenced in the document even if the witness does not refer to them in direct testimony. Counsel are reminded to have all witnesses available to testify so as not to delay the proceedings. Counsel are also reminded that testimony not summarized in prehearing statements or supplements thereto may be excluded at the hearing.

### IV. DOCUMENTS

Counsel for both parties intend to offer into evidence the documents identified in their respective prehearing statements. No later than 4:00 p.m. eastern standard time on March 19, 2007, counsel are to provide to each other copies of all documents listed in their respective prehearing statements and supplemental prehearing statements.

Both counsel are reminded that documents not listed in prehearing statements or supplements thereto or not timely supplied to the opposing party may be excluded at the hearing. At the hearing, counsel are to supply to the undersigned an extra copy of each document to be offered in evidence and/or shown to a witness. Counsel are to ensure that all documents consisting of five or more pages have all pages consecutively numbered.

### V. HEARING

Pursuant to 21 C.F.R. § 1316.44 (2006), and 21 C.F.R. § 1316.53 (2006), regulatory provisions requiring publication of the time and place of the hearing in the *Federal Register* are waived. The hearing will commence in either Tampa, Florida, or Sarasota, Florida, at 9:30 a.m. on July 10, 2007. The parties will be advised of the exact courtroom location as soon as arrangements have been completed. It is anticipated that the hearing will proceed through July 12, 2007 and will resume on July 24, 2007 and continue through July 26, 2007. Counsel are to meet the courtroom clerk in the courtroom at 9:00 a.m. on the morning of July 10, 2007, to have exhibits marked.

### VI. OTHER MATTERS

Counsel should note that this office will not accept filings by facsimile of more than twenty pages.

Dated: November 27, 2006

Un Betterer

Administrative Law Judge

### CERTIFICATE OF SERVICE

This is to certify that the undersigned on November 27, 2006, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara PC, 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Jarhie L. Stulin

Law Clerk to Mary Ellen Bittner Administrative Law Judge

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PAGE 01/04

### U.S. Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tel. (202) 307-8188 Fax 307-8198

## **FAX TRANSMISSION**

Date:

January 19, 2007

To:

John A. Gilbert, Jr., Esq.

Fax:

202-737-9329

Re:

In the Matter of McKesson Corporation d/b/a McKesson Drug Company

Sender:

Jamie Stulin

Attorney Advisor

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## UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In The Matter of	)	
	)	
McKesson Corporation	<b>)</b>	Docket No. 06-66
d/b/a McKesson Drug C	ompany )	
	)	

# MOTION FOR EXTENSION OF TIME TO FILE SUPPLEMENTAL PREHEARING STATEMENTS AND EXCHANGE DOCUMENTARY EVIDENCE

McKesson Corporation (Respondent), through the undersigned counsel, files this motion for an extension of time for the parties to file supplemental prehearing statements and exchange documentary evidence. Given that the hearing in this matter is not scheduled to begin until July 10, 2007, neither party will be prejudiced by extending the time to file this information. Respondent requests that the ALJ provide the parties with an extension of time until April 15, 2007 to file a supplemental prehearing statement and to exchange documents.

Respectfully submitted,

John A. Gilbert, Jr.

Hyman, Phelps & McNamara PC

700 Thirteenth Street, N.W.

MARA & Houle for

Washington, D.C. 20005

(202) 737-5600

(202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: March 16, 2007

### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on March 16, 2007, caused a copy of the foregoing to be delivered by facsimile and by hand to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be sent by facsimile and first class mail to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

Kathleen McKinley



LAW OFFICES

### HYMAN, PHELPS & MCNAMARA, P.C.

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Tel. No.: (202) 737-5600

Fax No.: (202) 737-9329

FROM:

John Gilbert

DATE:

March 16, 2007

TO:

Honorable Mary Ellen Bittner

FAX NO.:

(202) 307-8198

Wayne Patrick

(202) 307-4946

NO. OF PAGES (including this page): 💍

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### UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

### RULING ON REQUESTED EXTENSION

On March 16, 2007, counsel for Respondent filed a request for an extension of time for the parties to file supplemental prehearing statements and exchange documentary evidence in the above-captioned matter. Counsel for Respondent advised in a phone conversation with this office on March 16, 2007, that counsel for the Government does not oppose the extension.

Inasmuch as it appears that no prejudice will result, Respondent's request is granted. Accordingly, both parties may file their supplemental prehearing statements and exchange documentary evidence no later than 4:00 p.m. eastern daylight time on April 16, 2007.

Dated: March 16, 2007

Mary Ellen Bittner

Lee Stulie

Administrative Law Judge

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#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on March 16, 2007, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Jamie IJ. Stulin

Attorney Advisor to Mary Ellen Bittner

Administrative Law Judge

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PAGE 01/03

### U.S. Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tel. (202) 307-8188 Fax 307-8198

## **FAX TRANSMISSION**

Date:

March 16, 2007

To:

John A. Gilbert, Jr., Esq.

Wayne M. Patrick, Esq.

Fax:

202-737-9329

7-4946

Re:

In the Matter of McKesson Corporation, d/b/a McKesson Drug Company

Docket No. 06-66

Sender:

Jamie Stulin

Attorney Advisor to Mary Ellen Bittner

Chief Administrative Law Judge

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Please see attached "Ruling on Requested Extension."

Attachment

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Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tcl. (202) 307-8188 Fax 307-8198

## **FAX TRANSMISSION**

Date:

June 7, 2007

To:

John A. Gilbert, Esq.

Wayne Patrick, Esq.

Fax:

202-737-9329

7-4946

Re:

In the Matter of McKesson Corporation, d/b/a McKesson Drug Company

Docket No. 06-66

Sender:

Patricia Medessi /

Secretary to Mery Ellen Bittner Chief Administrative Law Judge

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Please see attached "Memorandum to Counsel."

Attachment

## UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

### MEMORANDUM TO COUNSEL

In my Prehearing Ruling issued on November 27, 2006 in the above-captioned matter, I directed counsel for both parties to file supplemental prehearing statements no later than March 19, 2007. I subsequently extended that filing deadline to April 16, 2007, following a motion from Respondent. As of June 7, 2007, neither party has filed a supplemental prehearing statement.

Counsel may have until 4 p.m. eastern daylight time on June 14, 2007 to advise me why I should not terminate this proceeding so that the Deputy Administrator may issue a final order.

Dated: June 7, 2007

Mary Elen Bittner

Administrative Law Judge

len Bettner

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on June 7, 2007, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Patricia A. Medico
Secretary to Mary Ellen Bittner
Administrative Law Judge

06/07/2007 15:14

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PAGE 01/03

### U.S. Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tel. (202) 307-8188 Fax 307-8198

## **FAX TRANSMISSION**

Date:

June 7, 2007

To:

John A. Gilbert, Jr., Esq. Wayne M. Patrick, Esq.

Fax:

202-737-9329

7-4946

Re:

In the Matter of McKesson Corporation, d/b/a McKesson Drug Company

Docket No. 06-66

Sender:

Jamie Stulin

Attorney Advisor to Mary Ellen Bittner

Chief Administrative Law Judge

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Please see attached "Memorandum to Counsel."

### UNITED STATES DEPARTMENT OF JUSTICE **Drug Enforcement Administration**

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

#### MEMORANDUM TO COUNSEL

Pursuant to a telephonic conference with both parties, I hereby rescind the Memorandum to Counsel I issued on June 7, 2007, in which I instructed the parties to advise me why I should not terminate this proceeding.

Counsel for the Government shall file an amendment to his prehearing statement no later than 4 p.m. eastern daylight time on June 11, 2007, in which he identifies his expert witness, if any, and details the witness' testimony.

The hearing in this matter is scheduled for July 10-12, 2007, in Tampa, Florida, and will be continued on July 24-26, 2007, in Arlington, Virginia.

Dated: June 7, 2007

Administrative Law Judge

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### CERTIFICATE OF SERVICE

This is to certify that the undersigned on June 7, 2007, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Jamie L. Stulin

Attorney Advisor to Mary Ellen Bittner

Administrative Law Judge

## Activity Report - Colve

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724	514	Jun-06	15:33	01/20 01/23	004	3016815968			EC 502		OK	
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738	530	Jun-07	18:06	00/37	004	111111111			EC 603		OK	
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742	536	Jun-09	21:36	01/03	001				EC 612		86	00
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# UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

MCKESSON CORPORATION

dba

MCKESSON DRUG COMPANY

Docket No. 06-23

### GOVERNMENT SUPPLEMENTAL PREHEARING STATEMENT

Pursuant to the June 7, 2007, Order of the Administrative Law Judge, the United States Department of Justice, Drug Enforcement Administration, by and through its undersigned attorney, hereby submits this supplement to its prehearing statement.

### PROPOSED WITNESSES

Diversion Investigator Scott Davis

[Will testify as previously noticed]

Diversion Investigator Shirley Scott

[Will testify as previously noticed]

Lisa Sullivan

[Will testify as previously noticed]

Diversion Investigator Michael Mapes

[Will testify as previously noticed]

George Van Komen, M.D.

[As described below]

Carmen Catizone, R.Ph.

P.02/07

### PROPOSED TESTIMONY

### Staff Coordinator Lisa Sullivan's Proposed Testimony

Staff Coordinator Sullivan will testify as previously noticed.

She will further testify that a review of ARCOS data for the first four months of 2007 indicated that in January 2007 McKesson-Lakeland had provided over 68,000 dosage units of hydrocodone to the internet pharmacy operation YPM Total Care Pharmacy, YPM's DEA registration was suspended in early 2007

### Pharmacy Expert Carmen Catizone Proposed Testimony

The Government will not present the in-person testimony of a pharmacist in the area of dispensing practice, but will present the curriculum vitae and transcript of the testimony of Dr. Catizone In the Matter of United Prescription Services, Inc. (United). This testimony focuses generally on the concept of prescribing and dispensing practices, including the provision of controlled to remote patients, by doctors not otherwise practicing in that State.

The testimony will further indicate that Dr. Catizone has previously testified in another DEA internet matter where he described the duties of pharmacist in dispensing controlled substances. He will describe factually relevant scenarios involving the dispensing practices of the Internet pharmacies and will testify as to whether and how such practices are suspicious and indicative of potential diversion of controlled substances.

His testimony will describe the standard of practice and usual course of business observed by pharmacists and pharmacies when purchasing and dispensing controlled substances. He will testify regarding the concept of corresponding responsibility attaching to pharmacists when dispensing physicians' prescriptions.

He will testify regarding physicians' prescription patterns and United's corresponding dispensing patterns with regard to controlled substances and opine on Respondent's purchasing patterns of all dangerous drugs as demonstrated by a review of its distributor records and opine how this compares to known industry walk-in retail pharmacies and known industry mail order pharmacies. The expert will conclude that the internet pharmacy operation as operated by United does not fit the model of a retail pharmacy and apparently is engaged in dispensing narcotics predominantly to individuals, in amounts not consistent with known demand to retail or mail order pharmacies and by use of prescription authorizations not sufficiently documented to ensure that the pharmacy meets its corresponding responsibility to ensure the substances are for legitimate therapeutic purposes and in the course of professional medical practice.

### Medical Expert George Van Komen [transcript of prior testimony]

The Government will not present the in-person testimony of a medical expert in the area of prescribing practice, but will present the curriculum vitae and transcript of the testimony of Dr. Van Komen In the Matter of Trinity Healthcare,

Inc. This testimony focuses generally on the concept of prescribing practices, including the provision of controlled to remote patients, by doctors not otherwise practicing in that State.

### DOCUMENTARY EVIDENCE [AMENDED]

- 1. Facsimile copy of DEA Certificate of Registration (McKesson-Lakeland)
- 2. Copy of DEA notice in 66 Fed. Reg. 21181, dated April 27, 2001
- 3. Charts- <u>Pharmacy Rankings for Hydrocodone</u>, October 2005-Janaury 2006 (9 pages)
- Charts- Accumed <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- 5. Charts- Avec <u>ARCOS purchases from McKesson</u>. October 2005-Janaury 2006 (9 pages)
- 6. Charts- Bi-Wise <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- 7. Charts- Trelles <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- 8. Charts- United ARCOS purchases from McKesson, October 2005-January 2006 (9 pages)
- Charts- Universal <u>ARCOS purchases from McKesson</u>, October 2005-Janaury 2006 (9 pages)
- Charts- Medipharm <u>ARCOS purchases from McKesson</u>, October 2005-January 2006 (9 pages)
- 11. Chart- Accumed Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 12. Chart- Avee Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)

- 13. Chart- Bi-Wise Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 14. Chart- Trelles Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 15. Chart-United Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 16. Chart- Universal Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 17. Chart- Medipharm Comparison of hydrocodone purchases by pharmacy October 2005 to January 2006. (1 page)
- 18. Charts- State of Florida- Suppliers of Hydrocodone to Seven Florida Pharmacies October 31, 2005- January 31, 2006. (8 pages)
- 19. Accumed ARCOS purchases, October 2005-January 2006 (3 pages)
- 20. Spreadsheet-McKesson Arcos Distribution October 1-31, 2005. (208 pages)
- 21. Spreadsheet-McKesson Arcos Distribution 2006.
- 22. Compilation- McKesson Distribution of Hydrocodone ...to Florida Pharmacies October 1-31, 2005 (16 pages)
- 23. Compilation- McKesson Distribution of Hydrocodone by DEA Number Sort October 1-31, 2005 (19 pages)
- 24. Chart- McKesson Hydrocodone Sales October 1-31, 2005. (2 pages)
- 25. Spreadsheet-McKesson Suspicious Purchase Report, October-November 2005. (27 pages)
- 26. DEA Compilation Sheet- Erroneous DEA number Identification in reports submitted by McKesson -2006.
- 27. McKesson-Lakeland Master and Registration History (7 pages)
- 28. DEA *Memorandum* dated October 20, 2005 by Michael Mapes to J. Rannazzisi regarding McKesson meeting. (16 pages)

- 29. DEA *Memorandum* dated January 23, 2006 by Michael Mapes to J. Rannazzisi regarding McKesson meeting. (3 pages)
- 30. ARCOS sales data for hyrocodone by McKesson-Lakeland January to April 2007. (68 pages)
- 31. DEA Charts: 2006 hydrocodone purchases by 61,584 pharmacies. (5 pages)
- 32. Testimony of Carmen Catizone, April 10, 2007, In the Matter of United Prescription Services. (Pages 304-378)
- 33. Biography/CV-Dr. Carmen Catizone (22 pages)
- 34. CV- Dr. George Van Komen
- 35. Testimony of George Van Komen, June 1, 2006, In the Matter of Trinity Healthcare Systems. (Pages 550-616)
- 36. Declaration of George Van Komen, February 22, 2006 (17 pages
- 37. William R. Lockridge, M.D. 71 Fed. Reg. 77,791 (2006)

Respectfully submitted,

Wayne M. Patrick

Attorney, Office of Chief Counsel

Dated: June 12, 2007

### CERTIFICATE OF SERVICE

On June 12, 2007, I sent via facsimile and mailed a copy of the foregoing, postage prepaid, to Counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman Phelps & McNamara, P.C., 700 13<sup>th</sup> Street N.W., Washington,

D.C. 20005

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### Activity Report





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Line I : 2027379329

Machine ID : HYMAN, PHELPS & McKAMARA, P.C.

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UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

Office of Adminis

Law Judge

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In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

### SUPPLEMENTAL PREHEARING STATEMENT OF MCKESSON CORPORATION

John A. Gilbert, Jr. Hyman, Phelps & McNamara PC 700 Thirteenth Street, N.W. **Suite 1200** Washington, D.C. 20005 (202) 737-5600 (202) 737-9329 (Fax)

## SUPPLEMENTAL PREHEARING STATEMENT OF MCKESSON CORPORATION

McKesson Corporation ("McKesson") by and through the undersigned counsel, respectfully submits this supplement to its prehearing statement.

### PROPOSED TESTIMONY

### 1. Additional Proposed Testimony of William Mahoney

Mr. Mahoney will testify as previously noticed.

Mr. Mahoney will further testify as to McKesson's Lakeland DC continued efforts to monitor distributions of controlled substances to pharmacy customers. Mr. Mahoney will testify as to the Lakeland DC's implementation of the Lifestyle Drug Monitoring Program. He will also testify as to recent contacts with DEA Group Supervisor Ken Boggess in regard to reporting of excessive purchases by customers based on McKesson's daily dosage report. Mr. Mahoney will also testify about McKesson's sales of controlled substances to YPM Total Care Pharmacy.

### 2. Additional Proposed Testimony of Donald Walker

Mr. Walker will testify as previously noticed.

Mr. Walker will further testify as to McKesson's efforts to monitor distributions of controlled substances to pharmacies across all of the McKesson DCs. He will also testify about McKesson's implementation of the Lifestyle Drug Monitoring Program. He will discuss the process for identifying purchases that

exceed the 8,000 dosage threshold for certain lifestyle drugs. He will discuss McKesson's procedures for conducting additional due diligence on customers who exceed the threshold.

# RESPONDENT'S PROPOSED SUPPLEMENTAL DOCUMENTARY EXHIBITS

- 64. McKesson Report of purchases of hydrocodone Augusts 2005 (Run date October 10, 2005.)
- 65. Government Contact between Bill Mahoney and D. Butcher re Lexus Drugs.
- 66. Government Contact with Miguel Soloraz, DEA dated January 19, 2005.
- 67. Letter from Brian Westmoreland to Janice Barnes, DEA re LPE Pharmacy, dated September 18, 2006.
- 68. Letter from Bill Mahoney to Ken Boggess, DEA dated March 16, 2007.
- 69. Letter from Bill Mahoney to Ken Boggess, DEA dated March 19, 2007.
- 70. Letter from Bill Mahoney to Ken Boggess, DEA dated March 21, 2007.
- 71. Letter from Bill Mahoney to Ken Boggess, DEA dated March 23, 2007.
- 72. Letter from Bill Mahoney to Ken Boggess, DEA dated April 3, 2007.
- 73. Letter from Bill Mahoney to Ken Boggess, DEA dated April 26, 2007.
  - 74. Lifestyle Drug Monitoring Program, McKesson Operations Manual.
  - 75. Excerpt from Daily Dosage Report for Lakeland DC.

- 76. Lifestyle Drug PowerPoint Presentation.
- 77. McKesson letter to Pharmacy Chain Accounts.
- 78. Lifestyle Drug Declaration Form.
- 79. Lifestyle Drug Pharmacy Questionnaire.
- 80. YPM Pharmacy response to Internet Questionnaire.

Respectfully submitted,

Yotm A. Gi∫bert∫Jr.

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Date: June 13, 2007



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June 13, 2007

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Helen Farmer
Hearing Clerk
Office of Administrative Law Judges
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, VA 22202

Re: In the matter of McKesson Corporation, d/b/a McKesson Drug Company,

Docket No. 06-66.

Dear Ms. Farmer:

Pursuant to 21 C.F.R. § 1316.52(d), McKesson Corporation ("McKesson"), Respondent in the above-captioned action, respectfully requests the issuance of a subpoena to compel the attendance of the individual identified below at the administrative hearing in the above-captioned matter scheduled to begin on July 10, 2007 in Tampa, Florida.

Debra Butcher
Diversion Investigator
Drug Enforcement Administration
Tampa District Office
4950 W. Kennedy Blvd., Suite 400
Tampa, Florida 33609
(813)287-4765
(813) 287-4766

Ms. Butcher is an employee of the Drug Enforcement Administration and has been identified as a Respondent witness in its prehearing statement.

2803 main Street Suite 780 Bryine, California 92814 1949: 553-7400 Fax: 1949: 553-7433 4816 Emperor Boulevard Suite 400 Durham, North Carolina 27703 1846/313-4750 Fax: 1848/313-4751 Helen Farmer June 13, 2007 Page 2

HYMAN, PHELPS & MCNAMARA, P.C.

Please let me know if you have any questions.

John A. Gillert, Jr.

Counsel to McKesson Corporation

cc: Wayne Patrick, Esq.

Office of Diversion & Regulatory Litigation Section

Office of Chief Counsel

Drug Enforcement Administration



LAW OFFICES

## HYMAN, PHELPS & MCNAMARA, P.C.

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Helen Farmer

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June 13, 2007

Wayne Patrick Diversion and Regulatory Litigation Section Office of Chief Counsel Drug Enforcement Administration 600 Army-Navy Drive Arlington, Virginia 22202

In the matter of McKesson Corporation, Docket No. 06-66 RE:

Mr. Patrick:

JOHN A. GILBERT, JR.

Please find enclosed copies of the documents identified in Respondent's prehearing statement and its supplemental prehearing statement filed with the Administrative Law Judge today.

Respondent will provide copies of several documents not included in the attachment as soon as they are available. In addition, Respondent may not offer all of the documents identified in its prehearing statement and supplemental prehearing statement. I will provide a list of those documents prior to the hearing.

Please do not hesitate to contact me should you have any additional questions.

2803 MAIN STREET SUITE 760 IRVINE CALIFORNIA 92814 19451 553 - 7400 FAX: (949) 553-7433

AND EMPEROR BOULEVARD SUME 400 DURHAM, NORTH CAROLINA 27703 1919) 313-4750 FAX (010) 313-4751

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Helen Farmer
Hearing Clerk
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Arlington, VA 22202

Re.

IOHN'A GERERT IR

In the matter of McKesson Corporation, d/b/a McKesson Drug Company,

Docket No. 06-66.

Dear Ms. Farmer:

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Debra Butcher
Diversion Investigator
Drug Enforcement Administration
Tampa District Office
4950 W. Kennedy Blvd., Suite 400
Tampa, Florida 33609
(813)287-4765
(813) 287-4766

Ms. Butcher is an employee of the Drug Enforcement Administration and has been identified as a Respondent witness in its prehearing statement.

2003 main Street Suite 700 (Rvine California 92014 1940) 553-7400 Fax: 1940) 563-7433 4819 EMPEROR BOULEVARD SUITE 400 DURHAM. NORTH CAROLINA 27703 1919: 313-4750 FAX: 1919: 313-4751 Helen Farmer June 13, 2007 Page 2 HYMAN, PHELPS & MCNAMARA, P.C.

Please let me know if you have any questions.

John A. Gilbert, Jr.

Counsel to McKesson Corporation

cc: Wayne Patrick, Esq.

Office of Diversion & Regulatory Litigation Section

Office of Chief Counsel

Drug Enforcement Administration

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In The Matter of	_ )	Law Auder Brug Anformant Administral
McKesson Corporation d/b/a McKesson Drug Company	) )	Docket No. 06-66

#### MOTION TO FILE SUPPLEMENTAL PREHEARING STATEMENT

McKesson Corporation (Respondent), through the undersigned counsel, files this motion to supplement its prehearing statement in the above captioned matter.

On June 7, 2007 the Administrative Law Judge ordered the Government to amend its prehearing statement to identify its expert witness, if any, and details of the witness's testimony. On June 12, 2007, Government counsel provided Respondent with a supplemental prehearing statement.

The Government's supplemental prehearing statement identifies Carmen Catizone as an expert witness that will testify based on a transcript from a prior matter. The Government has also listed a new witness, George Van Komen, M.D., who will also testify by transcript from a prior matter. The government has also provided additional testimony for a previously noticed witness, Lisa Sullivan. Finally, the Government has proposed eleven additional documents to be introduced at the hearing.

Therefore, Respondent now moves the ALJ to supplement its prehearing statement as described in the attached supplemental prehearing statement. The Government provided the transcript of Mr. Catizone's testimony, however, it has not as yet provided a

copy of the transcript of Dr. Van Komen. Respondent may request to further supplement its prehearing statement once it receives a copy of the transcript and can determine the scope of Dr. Van Komen's transcript testimony.

Respectfully submitted,

John A. Gilbert Jr.

Hyman, Nelps & McNamara PC 700 Thirteenth Street, N.W.

Washington, D.C. 20005

(202) 737-5600

(202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: June 13, 2007

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on June 13, 2007, caused a copy of the foregoing to be delivered by hand to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be delivered by hand to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

Kathleen McKinley





#### UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

DOCKET NO. 06-66

McKesson corporation p/b/a McKesson Drug Company

CONSENT MOTION TO RESCHEDULE HEARING DATES

D. LINDEN BARBER
ASSOCIATE CHIEF COUNSEL
OFFICE OF CHIEF COUNSEL
2401 JEFFERSON DAVIS HIGHWAY
ALEXANDRIA, VA 22301
VOICE: (202) 307-8010
FAX: (202) 307-4946



The United States Department of Justice, Drug Enforcement Administration

(Government), by and through its undersigned attorney, hereby submits this Consent Motion to Reschedule Hearing Dates.

In support of the Consent Motion, the Government offers the following:

- Government Counsel and Respondent's Counsel have engaged in settlement discussions regarding this matter. The Parties mutually desire to continue settlement discussions.
- 2. On June 21, 2007, Government Counsel contacted Respondent's Counsel, Mr. Douglas Farquhar, who consented to the request for continuance. After this discussion with Mr. Farquhar, Government Counsel contacted the Administrative Law Judge who indicated that, if this matter were continued, the Administrative Law Judge could docket this matter for hearing on October 30, 2007, with a second week of hearing beginning November 27, 2007.
- On June 25, 2007, Government Counsel contacted Respondent's Counsel who
  consented to the Government's request to seek a continuance of the hearing in this matter until
  October 30, 2007.

In consideration of the foregoing, the Government requests, with the consent of Respondent, that the hearing in this matter currently scheduled to begin July 10, 2007, in Tampa, Florida, be rescheduled in accordance with the Administrative Law Judge's docket. The Parties request that the hearing be scheduled to commence on October 30, 2007, if the Administrative Law Judge's calendar permits. If a second week of hearing is needed, the Parties request that the second week of hearing be set for November 27, 2007. This request is not sought for purposes of undue delay.

WHEREFORE, the Government requests that the Administrative Law Judge cancel the hearing in this matter scheduled to commence July 10, 2007, and reschedule the hearing for



October 30, 2007, or as soon thereafter as possible. Government counsel further asks the

Administrative Law Judge to schedule a conference call with counsel to discuss scheduling.

Respectfully submitted,

D. Linden Barber

Associate Chief Counsel

**Drug Enforcement Administration** 

Date: June 25, 2007

#### CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing CONSENT MOTION TO RESCHEDULE HEARING DATES IN THE MATTER OF MCKESSON CORPORATION D/B/A MCKESSON DRUG COMPANY, to be hand delivered to the DEA Office of the Administrative Law Judges; and I caused a copy of the foregoing to be mailed, via first-class postage prepaid mail, to Respondent's counsel at the following address:

Doug Farquhar, Esq. & John A. Gilbert, Jr., Esq. Law Offices of Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W. Suite 1200 Washington, DC 20005-5929

AND TO BE FAXED to Respondent's counsel, Doug Farquhar, Esq. & John A. Gilbert, Jr., Esq., at the following number: (202) 737-9329.

6-25-07

Date

A. Az. Bal





# UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

MCKESSON CORPORATION

dba

Docket No. 06-23

MCKESSON DRUG COMPANY

#### NOTICE OF APPEARANCE

The undersigned David Linden Barber hereby notices his appearance in this matter as co-counsel for the Government. All filings and notices should continue to be sent to the attention of the lead Government Counsel, Mr. Wayne Patrick.

Respectfully submitted,

D. Linden Barber

Associate Chief Counsel

Office of Chief Counsel

Co-Counsel for the Government

Dated: June 25, 2007

#### CERTIFICATE OF SERVICE

On June 25, 2007, I mailed a copy of the foregoing, postage prepaid, to Counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman Phelps & McNamara, P.C., 700 13<sup>th</sup> Street N.W., Washington, D.C. 20005

D. Linden Barber

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# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

#### MEMORANDUM TO COUNSEL AND ORDER

On June 25, 2007, counsel for the Government filed a motion to reschedule the hearing in the above-captioned matter. Counsel for the Government noted that he and counsel for Respondent are engaged in settlement discussions, and he therefore requests that the hearing be rescheduled for the weeks of October 30 and November 27, 2007. Counsel for the Government advised that counsel for Respondent consents to the motion.

Inasmuch as settlement discussions are underway, I grant the Government's motion. Accordingly, it is ORDERED that the hearing currently scheduled for July 10-12, 2007, and July 24-26, 2007, is cancelled and rescheduled for October 30-November 1, 2007, and November 27-29, 2007, in Tampa, Florida or Arlington, Virginia. My law clerk will schedule a conference call to discuss scheduling matters.

Dated: June 26, 2007

Møry ElÆn Bittner Administrative Law Judge

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LJ

PAGE 03/03

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on June 26, 2007, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Patricia A. Medico

Secretary to Mary Ellen Bittner Administrative Law Judge 06/26/2007 15:05

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LJ

PAGE 01/03

#### U.S. Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
Tel. (202) 307-8188 Fax 307-8198

# **FAX TRANSMISSION**

Date:

June 26, 2007

To:

John A. Gilbert, Jr., Esq.

Wayne Patrick, Esq.

Fax:

202-737-9329

7-4946

Re:

In the Matter of McKesson Corporation, d/b/a McKesson Drug Company

Docket No. 06-66

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Patricia Medla W/ 对从

Secretary to Mary Ellen Bittner Chief Administrative Law Judge

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Please see attached "Memorandum to Counsel and Order."

Attachment

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### MEMORANDUM TO COUNSEL

Pursuant to the discussion in a telephonic conference on September 6, 2007, the initial phase of the above-captioned hearing is scheduled from October 30-November 1, 2007 in Arlington, Virginia. As also discussed, counsel are to exchange documents they intend to introduce into evidence no later than 4:00 p.m eastern daylight time on October 12, 2007. If counsel intend to submit supplemental prehearing statements, they must do so no later than 4:00 p.m eastern daylight time on October 12, 2007.

Dated: September 10, 2007

Mary Elfen Bittner

Administrative Law Judge

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on September 10, 2007, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid to counsel for Respondent, John A. Gilbert, Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Attorney Advisor to Mary Ellen Bittner

Administrative Law Judge

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

	***	
In The Matter of	)	
	)	
McKesson Corporation	)	Docket No. 06-66
d/b/a McKesson Drug Company	)	
	)	

# JOINT MOTION FOR EXTENSION OF TIME TO FILE SUPPLEMENTAL PREHEARING STATEMENTS AND EXCHANGE DOCUMENTARY EVIDENCE

McKesson Corporation (Respondent), through the undersigned counsel, files this joint motion for an extension of time for the parties to file supplemental prehearing statements and exchange documentary evidence. On September 10, 2007, the ALJ issued a Memorandum to Counsel stating that the parties should exchange documents and file supplemental prehearing statements by October 12, 2007.

The parties are continuing to discuss a resolution to this matter. Therefore, the parties request a one week extension until October 19, 2007 to exchange documentary evidence and file supplemental prehearing statements. Respondent has discussed this motion with government counsel and they have agreed to the motion.

Respectfully submitted,

John A. Gilbert Jr.
Hyman, Phelps & McNamara PC
700 Thirteenth Street, N.W.
Washington, D.C. 20005
(202) 737-5600

(202) 737-3600 (202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: October 12, 2007

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on October 12, 2007, caused a copy of the foregoing to be delivered by facsimile with a confirmation copy by mail to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be delivered by facsimile to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

Kathleen McKinley



LAW OFFICES

## HYMAN, PHELPS 8 MCNAMARA, P.C.

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FROM:

John Gilbert

DATE:

October 12, 2007

TO:

Honorable Mary Ellen Bittner

FAX NO.:

(202) 307-8198

Wayne Patrick

(202) 307-4946

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LAW OFFICES

## HYMAN, PHELPS & MCNAMARA, P.C.

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Linden Barber

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#### UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### RULING ON REQUESTED EXTENSION

On October 12, 2007, counsel for Respondent filed a joint motion requesting an extension for filing supplemental prehearing statements and exchanging documentary evidence in the above-captioned matter. Counsel requests a one week extension from the October 12 deadline so that the parties can continue to discuss a resolution. Counsel for Respondent advised that counsel for the Government does not oppose the extension.

Inasmuch as it appears that no prejudice will result, Respondent's request is granted. Accordingly, the deadline for exchanging documentary evidence and filing supplemental prehearing statements is extended to October 19.

Dated: October 12, 2007

Mary Ellen Bittner Administrative Law Judge

Ellen Bittner

<sup>&</sup>lt;sup>1</sup> All dates herein are 2007.

#### CERTIFICATE OF SERVICE

This is to certify that the undersigned on October 12, 2007, caused a copy of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Attorney Advisor to Mary Ellen Bittner

Administrative Law Judge

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UNITED STATES

DRUG ENFORCEMENT AND COLLABORATER SUBJECT |

NEW 7540-01-317-7888 SQUIL-DIX GENERAL SERVICES ADMINISTRATION

IN THE MATTER OF

MCKESSON CORPORATION

d/b/2

MCKESSON DRUG COMPANY

Docket No. 06-23

### GOVERNMENT SUPPLEMENTAL PREHEARING STATEMENT

The United States Department of Justice, Drug Enforcement

Administration, by and through its undersigned attorney, hereby submits this supplement to its prehearing statement. All witnesses, proposed testimony, and documentary evidence previously noticed remain unchanged. The following new matters are presented.

#### PROPOSED WITNESSES

Joseph T. Rannazzisi
Deputy Assistant Administrator
Drug Enforcement Administration

[As described below]

Barbara Boockholdt Staff Coordinator Drug Enforcement Administration [As described below]

William Mahoney
Distribution Center Manager
McKesson Corporation

[As described below]

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OFC OF CC (GCD-CCR)

PAGE 02/05

Donald Walker Senior Vice President McKesson Corporation [As described below]

#### PROPOSED TESTIMONY

Joseph T. Rannazzisi

Mr. Rannazzisi will testify regarding his professional background and experience, and the following: 1) that he met with McKesson officials in January 2006 regarding McKesson's extraordinarily large distributions of hydrocodone, and select other controlled substances to pharmacies under circumstances that indicated that the pharmacies were diverting controlled substances; 2) that he asked the McKesson representatives if they could give him any reason why DEA should not revoke McKesson's registration, and the McKesson officials did not explain why their large distributions to pharmacies under suspicious circumstances; 3) that after the January 2006 meeting, McKesson continued to distribute controlled substances under circumstances that were indicative of diversion; 4) the national problem regarding the diversion of hydrocodone and benzodiazepines; 5) the efforts that DEA has taken to educate distributors about the warning signs of diversion, and the efforts that DEA took to educate McKesson.

#### Barbara Boockholdt

Ms. Boockholdt will testify regarding her professional background and experience, and the following: 1) that McKesson's distributions of hydrocodone to certain Florida pharmacies were significantly greater than any distributions that she has ever seen for legitimate purposes; 2) that DEA has taken administrative action against or received surrenders of registrations from some of McKesson's largest purchasers of hydrocodone; 3) that information was available on the Internet through simple use of a search engine that could have alerted McKesson that certain pharmacy customers were purchasing hydrocodone to fill prescriptions issued by out-of-state physicians who never conduct an examination of the individual purchasing controlled substances.

#### William Mahoney

Mr. Mahoney will testify about McKesson's sales of hydrocodone and other drugs, controlled and non-controlled, to the pharmacles identified in the Order to Show Cause, and its drug distributions to YPM and Mai Pharmacy. Mr. Mahoney will testify about how the orders from those

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PAGE 03/05

pharmacies compare to the orders placed with McKesson by other retail pharmacies. He will testify about that the orders of hydrocodone by those pharmacies were of an unusual size, an unusual, frequency, or deviated from the normal pattern of orders by retail pharmacies, or a combination of more than one of those factors. He will testify about the steps that McKesson undertook to ensure that those orders were legitimate before filling those orders. He will also testify about the attempts that DEA took to educate McKesson about the signs of diversion by pharmacies. He will testify about the timing and nature of the training and guidance that he received from McKesson's corporate headquarters regarding the rogue Internet pharmacies, signs of diversion, and McKesson's obligations as a DEA registrant. He will testify about the McKesson employees or agents who visited the pharmacies, what reports if any they made to him or other McKesson manager, and what actions McKesson took in response to those reports. He will also testify about the general operation of the Lakeland Distribution Center and other matters noticed in Respondent's prehearing statement. He will testify that after McKesson received the Order to Show Cause that it distributed a large amount of hydrocodone to YPM under suspicious circumstances. He will testify that he became aware of DEA's suspension of a major distributor in central Florida in April 2007. Notwithstanding his knowledge of this, McKesson supplied an unusually large amount of hydrocodone to Mai pharmacy in June and July of 2007, and later determined that McKesson should no longer sell to Mai Pharmacy.

#### Donald Walker

Mr. Walker will testify about McKesson's sales of hydrocodone and other drugs, controlled and non-controlled, to the pharmacies identified in the Order to Show Cause, and its drug distributions to YPM and Mai Pharmacy. He will testify about the steps that McKesson undertook to ensure that its managers and employees were promptly trained on the diversion concerns that DEA brought to McKesson's attention in September 2005. He will testify about the role of McKesson's corporate headquarters in making decisions about the sales of controlled substances to pharmacies, and about all corporate policies related to diversion of controlled substances, and Internet diversion schemes in particular. He will also testify about the matters noticed in Respondent's prehearing statement.

DOCUMENTARY EVIDENCE

[AMENDED]

1-38. As previously noticed

3

- 39. Chart showing hydrocodone distributions by Respondent to Mai Pharmacy in 2006 and 2007.
- 40. Chart showing hydrocodone distributions by Respondent to YPM in 2006 and 2007.
- 41. Final Order, United Prescription Services, Inc.
- 42. Final Order, Southwood Pharmaceuticals, Inc.
- 43. Immediate Suspension Order, Avee Pharmacy
- 44. Immediate Suspension Order, YPM
- 45. Order to Show Cause, Trelles Pharmacy
- 46. Order to Show Cause, Bi-Wise Pharamcy
- 47. Immediate Suspension, Medipharm-Rx
- 48. Order to Show Cause, Accumed
- 49. Letter from Joseph Rannazzisi to McKesson dated September 26, 2006

#### OTHER MATTERS

The Government agrees to an extension of time for Respondent to file its Supplemental Prehearing Statement. The Government has no objection to Respondent filing its Supplemental Prehearing Statement any time prior beginning of the hearing.

Respectfully submitted,

D. Linden Barber

Associate Chief Counsel

Drug Enforcement Administration

Dated: September 19, 2007

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10/19/2007 18:13

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PAGE 05/05

#### CERTIFICATE OF SERVICE

On October 19, 2007, I sent via facsimile a copy of the foregoing, to

Counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman Phelps &

McNamara, P.C., 700 13th Street N.W., Washington, D.C. 20005.

D. Linden Barber

Associate Chief Counsel

Drug Enforcement Administration

# U.S. Department of Justice Drug Enforcement Administration Office of Chief Counsel

www.dea.gov

Washington, D.C. 20537

October 22, 2007

Honorable Mary Ellen Bittner DEA Office of Administrative Law Judges Washington, D.C. 20537

Re: In the Matter of McKesson Corporation, DEA Docket No. 06-23

To the Honorable Judge Bittner:

The Government requests that subpoenas be issued to compel the appearance and testimony of the following witnesses at Arlington, Virginia (estimated for October 30, 2007) and be tendered to the Government for appropriate service.

Donald G. Walker Senior Vice President McKesson Pharmaceutical One Post Street San Francisco, California 94104

William Mahoney Distribution Cneter Manager McKesson Drug Company 1515 West Bella Vista Street Lakeland, Florida 33805

Respectfully submitted

Wayne Hatrick

Counsel for the Government

ce: John A. Gilbert, Jr., Esq. F: (202) 737-9329





Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

October 22, 2007

Wayne Patrick, Esq.
Office of Chief Counsel
Drug Enforcement Administration
Washington, D.C. 20537

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

Dear Mr. Patrick:

On October 22, 2007, you filed a request for subpoenas in the above-referenced matter. Subpoenas for the following individuals are enclosed.

Donald G. Walker Senior Vice President McKesson Pharmaceutical One Post Street San Francisco, California 94104

William Mahoney
Distribution Center Manager
McKesson Drug Company
1515 West Bella Vista Street
Lakeland, Florida 33805

If you have any questions or need additional information, please contact my law clerk, Thomas 'Skip' Mark, at (202) 307-8188.

Sincerely,

Mary Ellen Bittner

Administrative Law Judge

Enclosures (2)

cc: John A. Gilbert, Jr., Esq. (w/o enclosures)





# United States Department of Justice

Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

October 23, 2007

John A. Gilbert, Jr., Esq. Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

#### Dear Counsel:

CC:

As you know, the hearing in this proceeding will be held at the Drug Enforcement Administration's (DEA) headquarters. The Office of Security Programs requires a list of all individuals attending the hearing other than DEA employees.

Please notify this office of all persons attending the hearing by 4:00 p.m. eastern daylight time on Wednesday, October 24, 2007. Please direct your response to the Hearing Clerk, Ms. Helen Farmer, and provide the individuals' full name and date of birth. Your prompt attention to this matter is greatly appreciated.

If you have any additional questions or concerns, please contact me at (202) 307-8188. Thank you for your cooperation.

Respectfully.

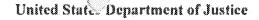
Thomas Skip Mark

Attomey Advisor to Mary Ellen Bittner

Administrative Law Judge

Wayne M. Patrick, Esq., Office of Chief Counsel Helen Farmer, Office of Administrative Law Judges





Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

October 23, 2007

Wayne M. Patrick, Esq.
Office of Chief Counsel
Drug Enforcement Administration
Washington, D.C. 20537

John A. Gilbert, Jr., Esq. Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

# Dear Counsel:

At Judge Bittner's direction, I am writing to advise you that the hearing scheduled to begin at 9:30 a.m. on October 30, 2007, will be held in the hearing room at the Drug Enforcement Administration's headquarters, 600 Army Navy Drive, Arlington, Virginia. The hearing is scheduled to last three days.

You are reminded to meet the law clerk at 9:00 a.m. on the first day of the hearing to have exhibits marked. Please bring an extra set of exhibits for the judge, and make certain that witnesses are available to testify without delay.

If you have any additional questions or concerns, please contact me at (202) 307-8188.

Respectfully,

Thomas Skip Mark

Law Clerk to Mary Ellen Bittner

Home Ellat

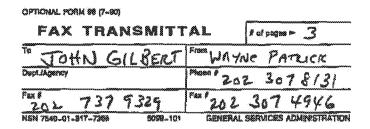
Administrative Law Judge

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PAGE 01/03



WE WILL ATTEMPT TO SERVE TOMORROW.

I WILL IDENTIFY POC FOR TRAVEL ANDANGEMENTS
TOMUNFOW.

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OFC OF CC (CCD-CCR)

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# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket No. 06-66

SUBPOENA

TO: William Mahoney
Distribution Center Manager
McKesson Drug Company
1515 West Bella Vista Street
Lakeland, Florida 33805

Request therefore having been duly made by Wayne Patrick, Esq., attorney for the Government, you are hereby commanded to appear in the hearing room at the Drug Enforcement Administration headquarters, 600 Army Navy Drive, Arlington, Virginia 22202 on Tuesday, October 30, 2007, at 9:30 a.m. to give testimony in this matter and not to depart without leave.

This subpoena is issued under the authority of the Controlled Substances Act, 21 U.S.C. §§ 875 and 876 (1996) and 21 C.F.R. § 1316.52(d) (2007).

Issued: October 22, 2007

Mary Effen Bittner

Administrative Law Judge

### NOTICE TO WITNESS:

You may be entitled to witness fees for your attendance, subsistence, and mileage under this subpocna and, if so, such fees are to be paid by the party at whose request this subpocna is issued. All arrangements for payment are to be made with that party.

P-00016 00148

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OFC OF CC (CCD-CCR)

PAGE 03/03

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/s McKesson Drug Company Docket No. 06-66

SUBPOENA

TO: Donald G. Walker
Senior Vice President
McKesson Pharmaceutical
One Post Street
San Francisco, California 94104

Request therefore having been duly made by Wayne Patrick, Esq., attorney for the Government, you are hereby commanded to appear in the hearing room at the Drug Enforcement Administration headquarters, 600 Army Navy Drive, Arlington, Virginia 22202 on Tuesday, October 30, 2007, at 9:30 a.m. to give testimony in this matter and not to depart without leave.

This subpoena is issued under the authority of the Controlled Substances Act, 21 U.S.C. §§ 875 and 876 (1996) and 21 C.F.R. § 1316.52(d) (2007).

Issued: October 22, 2007

Mary Ølen Bittner

Administrative Law Judge

## NOTICE TO WITNESS:

You may be entitled to witness fees for your attendance, subsistence, and mileage under this subpocna and, if so, such fees are to be paid by the party at whose request this subpocna is issued. All arrangements for payment are to be made with that party.

OFC OF CC (CCD-CCR)

PAGE 01/09

FAX TRANSMITTAL FOILBERT FOR WAYNE PATRICK

707 307 6737 7202 737 7325 Fax 202 307 4946 NBN 7640-01-217-7988 6098-101 GENERAL SERVICES ADMINISTRATIC

WE WILL ATTEMPT TO SERVE TOMORROW!

I WILL IDENTIFY ROC FOR TRAVEL ARMANGEMENTS

TO IN ULLOW.

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10/24 - LETTER WILL BE DELIVERED WITH SUMPORTA

DELORAH JURDAN WITH A COMPLETED W9 and completed FFS commenced worder record

Thank. Waye

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PAGE 02/09



# U.S. Department of Justice Drug Enforcement

Administration

Office of Chicf Counsel

www.dea.gov

Washington, D.C. 20537

October 24, 2007

William Mahoney
Distribution Center Manager
McKesson Drug Company
1515 West Bella Vista Street
Lakeland, Florida 33805

Dear Mr. Mahoney:

You have been served with a subpoens to appear to testify in the Government's case-in-chief in the matter of McKesson Drug Company on October 30, 2007 in Arlington, Virginia.

If you travel and appear in this proceeding, you may be entitled to Government paid travel, lodging, and certain expenses. However, in order to accomplish this, the DEA must issue you travel orders and must book your flight and lodging for you. In addition, any re-imbursement of expenses must be accomplished by direct deposit to a designated account of yours. In order to arrange this travel, please contact Ms. Deborah Jordan, DEA Office of Chief Counsel at (202) 307-3663.

You may elect to arrange for travel on your own, subject to reimbursement. However, claims for travel and lodging will be limited to reimbursement for coach travel and local area lodging rates at whatever ceiling has been established by Federal travel regulations or contracts.

If you have any questions regarding the subpoena itself, you may have your counsel contact me at (202) 307-8131.

**enceret** 

Wayne Patrick

Attorney

Drug Enforcement Administration

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OFC OF CC (CCD-CCR)

PAGE 03/09



# U.S. Department of Justice Drug Enforcement

Administration
Office of Chief Counsel

www.dea.gov

Washington, D.C. 20537

October 24, 2007

Donald G. Walker
Senior Vice President
McKesson Pharmaceutical
One Post Street
San Francisco, California 94104
(415 983- 7062/9060)

Dear Mr. Walker:

You have been served with a subpoena to appear to testify in the Government's case-in-chief in the matter of McKesson Drug Company on October 30, 2007 in Arlington, Virginia.

If you travel and appear in this proceeding, you may be entitled to Government paid travel, lodging, and certain expenses. However, in order to accomplish this, the DEA must issue you travel orders and must book your flight and lodging for you. In addition, any re-imbursement of expenses must be accomplished by direct deposit to a designated account of yours. In order to arrange this travel, please contact Ms. Deborah Jordan, DEA Office of Chief Counsel at (202) 307-3663.

You may elect to arrange for travel on your own, subject to reimbursement. However, claims for travel and lodging will be limited to reimbursement for coach travel and local area lodging rates at whatever ceiling has been established by Federal travel regulations or contracts.

If you have any questions regarding the subpoena itself, you may have your counsel contact me at (202) 307-8131.

Sincerely,

Wayne Patrick

Attorney

Drug Enforcement Administration

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OFC OF CC (CCD-CCR)

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Form W-9

Department of the Treasury

# Request for Taxpayer Identification Number and Certification

Give form to the requester. Do not send to the IRS.

imemai	Rovenus Service					
Petra curtypa See Specific Instructions on page 2.	Name					
	Business name, if different from gbove					
	Check appropriate box: ☐Sala proprietor ☐Corporation ☐Partnership ☐Other ▶ ☐ Exempt from backup withholding					
Man	Address (number, street, and apt, or suite no.) Requester's name and address (optional)					
pacific	City, stats, and ZIP code					
8	List account number(s) here (optional)					
Parti	Taxpayer Identification Number (TIN)					
Enter your TIN in the appropriate box. For individuals, this is your social security number (SSN).  However, for a resident alien, sole propriator, or disregarded entity, see the Part I instructions on page 3. For other antibias, it is your amployer identification number (EIN). If you do not have a number, see How to get a TIN on page 3.						
Note: to ent	If the account is in more than one name, see the chart on page 4 for guidalines on whose number Employer Identification number r.					
Pauli	Certification					

Under penalties of portury, I certify that:

- 1. The number shown on this form is my correct texpayer identification number (or I am welting for a number to be issued to ma). and
- I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the internal Revenue Service (IRS) that I am subject to backup withholding as a result of failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding, and
- 3. I am a U.S. person (including a U.S. resident alien).

Cartification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have falled to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement lifely, and generally, payments other than interest and dividends, you are not required to sign the Cartification, but you must provide your correct TIM. (See the instructions on page 4.)

Sign Signature of Harra U.S. person > Data >

# Purpose of Form

A person who is required to file an information return with the IRS, must obtain your correct taxpayer identification number (TIN) to report, for example, income paid to you, real estate transactions, mortgage interest you paid, acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA.

U.S. person. Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN to the person requesting it (the requester) and, when applicable, to:

- 1. Cartify that the TIN you are giving is correct (or you are waiting for a number to be issued),
- 2. Certify that you are not subject to backup withholding,
- or
  3. Claim exemption from backup withholding if you are a U.S. exempt payee.

Note: If a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

Foreign person. If you are a foreign person, use the appropriate Form W-8 (see Pub. 515, Withholding of Tax on Nonresident Aliens and Foreign Entities).

Nonresident alien who becomes a resident alien. Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treatles contain a provision known as a "saving clause." Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the recipient has otherwise become a U.S. resident allen for tax purposes.

- If you are a U.S. resident allen who is relying on an exception contained in the saving clause of a tex treaty to claim an exemption from U.S. tex on certain types of income, you must attach a statement that specifies the following five items:
- 1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident elien.
- 2. The treaty article addressing the income.
- 3. The article number (or location) in the tex treaty that contains the saving clause and its exceptions.
- 4. The type and amount of income that qualifies for the exemption from tax.

Sufficient facts to justify the exemption from tax under the terms of the treaty erticle.

Cat. No. 10231X

Form W-9 (Rev. 1-2003)

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Form W-9 (Rev. 1-2003)

Page 2

Example: Article 20 of the U.S. -China income tax tresty allows an examption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. Isw, this student will become a resident alian for tax purposes if his or her stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S. -China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alian of the United States. A Chinese student who qualifies for this exception (under paragraph 2 of the first protocol) and is relying on this exception to claim an examption from tex on his or her scholarship or fellowship income would attach to Form W-8 a statement that includes the information described above to support that exemption.

If you are a nonresident elien or a foreign entity not subject to backup withholding, give the requester the appropriate completed Form W-8.

What is backup withholding? Persons making certain payments to you must under certain conditions withhold and pay to the IRS 30% of such payments (29% after December 31, 2003; 28% after December 31, 2005). This is called "backup withholding." Payments that may be subject to backup withholding include interest, dividends, broker and barter exchange trensactions, rents, royalties, nonemployee pay, and certain payments from fishing bost operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester your correct TIN, make the proper certifications, end report all your taxable interest and dividends on your tax return.

Payments you receive will be subject to backup withholding if:

- 1. You do not furnish your TIN to the requester, or
- 2. You do not certify your TIN when required (see the Part II instructions on page 4 on details), or
- 3. The IRS tells the requester that you furnished an incorrect TIN, or
- 4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only), or
- 5. You do not certify to the requester that you are not subject to backup withholding under 4 above (for reportable interest and dividend accounts opened after 1983 only).

Certain payers and payments are exempt from backup withholding. See the instructions below and the separate instructions for the Requester of Form W-9.

#### **Penalties**

Failure to furnish TIN. If you fell to furnish your correct TIN to a requester, you are subject to a penalty of \$50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

Civil panalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a \$500 penalty.

Criminal penalty for faisifying information. Willfully faisifying certifications or affirmations may subject you to criminal penalties including fines end/or imprisonment.

Misuse of TiNs. If the requester discloses or uses TINs in violation of Federal law, the requester may be subject to civil and criminal penalties.

#### Specific instructions

#### Name

If you are an individual, you must generally enter the name shown on your social security card. However, if you have changed your last name, for instance, due to marriage without informing the Social Security Administration of the name change, enter your first name, the last name shown on your social security card, and your new last naw.

If the account is in joint names, list first, and then circle, the name of the person or entity whose number you entered in Part I of the form.

Sole proprietor. Enter your individual name as shown on your social security card on the "Name" line. You may enter your business, trade, or "doing business as (DBA)" name on the "Business name" line.

Limited liability company (LLC). If you are a single-member LLC (including a foreign LLC with a domestic owner) that is disregarded as a entity separate from its owner under Treasury regulations section 301.7701-3, anter the owner's name on the "Name" line. Enter the LLC's name on the "Business name" line.

Other entities. Enter business name as shown on required Federal tax documents on the "Name" line. This name should match the name shown on the charter or other legal document creating the entity. You may enter any business, trade, or DBA name on the "Business name" line.

Note: You are requested to check the appropriate box for your status (Individual/sole propriator, corporation, etc.)

#### **Exempt From Backup Withholding**

If you are exempt, enter your name as described above and check the appropriate box for your status, then check the "Exempt from backup withholding" box in the line following the business name, sign and date the form.

Generally, individuels (including sole proprietors) are not exempt from backup withholding. Corporations are exempt from back withholding for cartain payments, such as interest and dividends.

Note: If you are exempt from backup withholding, you should still complete this form to avoid possible erroneous backup withholding.

Exempt payees. Backup withholding is not required on any payments made to the following payees:

- An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(2);
- 2. The United States or any of its agencies or instrumentalities;
- 3. A state, the District of Columbia, a possession of the United States; or any of their political subdivisions or instrumentalities;
- 4. A foreign government or any of its political subdivisions, agencies, or instrumentalities; or
- 5. An international organization or any of its agencies or instrumentalities.

Other payees that may be exampt from backup withholding include:

- 6. A corporation;
- 7. A foreign central bank of issue:
- 8. A dealer in securities or commodities required to register in the United States, the District of Columbia, or a possession of the United States;

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PAGE 06/09

Form W-9 (Rev. 1-2003)

Fage 3

9. A futures commission merchant registered with the Commodity Futures Trading Commission;

#### 10.A real estate investment trust:

- 11.An entity registered at all times during the tax year under the investment Company Act of 1940;
- 12.A common trust fund operated by a bank under section 584(a);
  - 13.A financial institution:
- 14.A middleman known in the investment community as a nominee or custodien; or
- 15.A trust exempt from tax under section 684 or described in section 4947.

The chart below shows types of payments that may be exempt from backup withholding. The chart applies to the exempt recipients listed above, 1 through 15.

If the payment is for	THEN the payment is exempt for
Interest and dividend payments	All exempt recipients except for 9
Broker transactions	Exempt recipients 1 through 13. Also, a person registered under the investment Advisers Act of 1940 who regularly acts as a broker
Barter exchange transactions and patronage dividends	Exempt reciplents 1 through 5
Payments over \$600 required to be reported and direct sales over \$5,000 to	Generally, exempt reciplents 1 through 7

<sup>&</sup>lt;sup>1</sup> See Form 1099-MISC, Miscellaneous Income, and its instructions.

# Part I. Texpayer Identification Number (T(N)

Enter your TIN in the appropriate box. If you are a resident alien and you do not have and are not eligible to get an SSN, your TIN is your IRS individual taxpayer identification number (ITIN). Enter it in the social security number box. If you do not have an ITIN, see How to get a TIN below.

If you are a sole proprietor end you have an EIN, you may enter either your SSN or EIN. However, the IRS prefers that you use your SSN.

If you are a single-owner LLC that is disregarded as an entity separate from its owner (see Limited liability company (LLC) on page), enter your SSN (or EIN, if you have one). If the LLC is a corporation, partnership, etc., enter the entity's EIN.

Note: See the chart on page 4 for further clarification of name and TIN combinations.

How to get a TIN. If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local Social Security Administration office or get this form on-line at www.ssa.gov/online/ss5.html. You may also get this form by calling 1-800-772-1213. Use Form W-7. Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can get Forms W-7 and SS-4 from the IRS by calling 1-800-TAX-FORM (1-800-829-3676) or from the IRS Web Site at www.irs.gov.

if you are asked to complete Form W-9 but do not have a TIN, write "Applied For" in the space for the TIN, sign and date the form, and give it to the requester. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, generally you will have 50 days to get a TIN and give it to the requester before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requester.

Note: Writing "Applied For" means that you have already applied for a TIN or that you intend to apply for one soon.

Caution: A disregarded domestic entity that has a foreign owner must use the appropriate Form W-8.

<sup>&</sup>lt;sup>2</sup>However, the following payments made to a corporation (including gross proceeds, paid to an attorney under section 8045(f), even if the attorney is a corporation) and reportable on Form 1089-MISC are not exampt from backup withholding; medical and health care payments, attorneys' fees; and payments for services by a Federal executive agency.

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Form W-9 (Rev. 1-2003)

Page 4

#### Part II. Certification

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if items 1, 3, and 5 below indicate otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). Exempt recipients, see Exempt from backup withholding on Page 2.

Signature requirements. Complete the certification as indicated in 1 through 5 below.

- 1. Interest, dividend, and barter exchange accounts opened before 1984 and broker accounts considered active during 1983. You must give your correct TIN, but you do not have to sign the certification.
- 2. Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983. You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requester, you must cross out item 2 in the certification before signing the form.
- 3. Real estate transactions. You must sign the certification. You may cross out item 2 of the certification.
- 4. Other payments. You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. "Other payments" include payments made in the course of the requester's trade or business for rents, royalties, goods (other than bills of merchandise), medical and health care services (including payments to corporations), payments to nonemployee for services, payments to certain fishing bost crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).
- 5. Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tultion program payments (under section 529), IRA or Archer IMSA contributions or distributions, and person distribution. You must give your correct TIN, but you do not have to sign the certification.

### What Name and Number To Give the Requester

70	r this type of account:	Give name and SSN of:
1.	Individual	The individual
2.	Two or more individuals (joint account)	The actual owner of the account or, if combined funds, the first individual on the account
З.	Custodian account of a minor (Uniform Gift to Minors Act)	The minor <sup>2</sup>
4.	a.The usual revocable savings trust (grantor is also trustes)	The grantor-trustee 1
	b.So-called trust account that is not a legal or valid trust under state law	The sotuel owner <sup>1</sup>
5.	Sale proprietorship or single-owner LLC	The owner <sup>3</sup>
Fo	r this type of account:	Give name and EIN of:
8.	Sola propriatorahip or single-owner LLC	The owner <sup>3</sup>
7.	A Valid trust, estate, or pension trust	Legal entity 4
8,	Corporate or LLC electing carporate status on Form 8832	The corporation
9.	Association, club, religious, charitable, educational, or other tax-exempt organization	The organization
10	Partnership or multi-member LLC	The partnership
99	.A broker or registered nomines	The broker or nomines
12.	Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments	The public entity

<sup>&</sup>lt;sup>1</sup> Liet first and dirds the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.

Note: If no name is circled when more than one name is Ksted, the numbor will be considered to be that of the first name listed.

### **Privacy Act Notice**

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons who must file information returns with the IRS to report interest, dividends, and certain other income paid to you, mortgage interest you paid, the acquisition or abandonment of secured property, cancellation of debt, or contributions you made to an IRA or Archer MSA. The IRS uses the numbers for identification purposes and to help verify the accuracy of your tax return. The IRS may also provide this information to the Department of Justice for civil and criminal litigation, and to cities, states, and the District of Columbia to carry our their tax laws. We may also discloss this information to other countries under a tax treaty, or to Federal and state agencies to enforce Federal nontex criminal laws and to combat terrorism

You must provide your TIN whather or not you are required to file a tax return. Payers must generally withhold 30% of taxable interest, dividend, and certain other payments to a payer who does not give a TIN to a payer. Certain penalties may also apply.

 $<sup>^{\</sup>mathrm{Z}}$  Civale the minor's name and furnish the minor's SSN.

 $<sup>^3</sup>$  You must show your individual name, but you may also enter your business or "DBA" name. You may use alther your SSN or EIN lif you have one).

<sup>&</sup>lt;sup>4</sup> List first and circle the name of the legal trust, astate, or pension trust. IDo not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the economy title.)

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PAGE 08/09

U.S. DEPARTMENT OF JUSTICE - DRUG ENFORCEMENT ADMINISTRATION

# FFS COMMERCIAL VENDOR RECORD REQUEST FORM

# (CCR) Registration Exempt

(Read Instructions before completing)

• CHANGE []			source document must be attached h a document will not be processed.						
November 1980 - September 1980 - Vindo in Continuente de la Continuente de la Continuente de la Continuente de									
b. Payasa Nama			c. W-S Form must be etteched.						
		***************************************							
d. Remit to Address (if different a	uddress on W-9 form)	>	e. Tax Exempt?   YES L. NO						
9888			must be attached unless the vendor is a						
			Government Entity TYES NO						
t. City	g, State		h. Zip Code	***************************************					
	Standar Conf			***************************************					
L Name	j. Phone #		k. DEA Contact and Phone #	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
	Vendor Ulrect D	oposit hilom							
1. Financial Institution Name				skiekistäise					
m. City	n. Stete	a. Zip Code	p. Phone #						
	***************************************	000000000000000000000000000000000000000							
q. Nine Digit Routing Transit #		r. Account#		<u> </u>					
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	Andon Facora Re Wind Co. Company of the Co.	3 C	SENTER BEFORE SECTION OF THE PROPERTY OF THE SECTION OF THE SECTIO						
t. Printed Name		u. Spneture							
Deborah A. Jordan									
v. Title	***************************************		w. Phone #	***************************************					
Administrative Support Speciali	ist		202-307-3863						
x. DEA Office		·····	V. Date						
Chief Counsel		ï							
		000000000000000000000000000000000000000							

instructions for completion of this form are on back

Vendor - When completed, please FAX form to DEA contact.

Requester - When completed, please FAX form to Office of Finance, FNS (202)353-1134.

FORM DEA-1378 (03-04) Previous editions absolute

Electronic Form Version Designed in JetForm 5.2 Version

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OFC OF CC (CCD-CCR)

PAGE 09/09

# INSTRUCTIONS FOR COMPLETING FORM

A DEA Vendor Record must exist in order to process all obligations and payments for individual and Commercial/Governmental vendors except those where purchase and payment is executed via use of a purchase cerd. A properly completed form, containing the required information, submitted by a DEA employee will be the basis for creating a Federal Financial System (FFS) vendor record. The request form is subject to internal and external review.

# Who is exempt from CCR registration?

According to the DFARS 204.7302, NASA, DoJ, DoT and Treasury FAR Supplements prospective both current and potential government vendors are required to be registered in CCR to receive payment on a prior contract or prior to the award of a contract; basic agreement, basic ordering agreement, or blanket purchase agreement exceeding \$2,500. Exempt from CCR registration are vendors whose basic agreement is below \$2,500 and do not use the electronic funds transfer (EFT) method for payment and are not required to be reported; Also exempt are purchases that (1) Use a Government wise commercial purchase card as both the purchasing and payment mechanism; (2) Classified contracts; (3) Contracts awarded by—(i) Deployed contracting officers in the course of military operations, including but not limited to, contingency operations as defined in 10 U.S.C. 101(a)(13) or humanitarian or peacekeeping operations as defined in 10 U.S.C. 2303(7); or (ii) Contracting officers in the conduct of emergency operations, such as responses to natural or environmental disasters or national or civil emergencies, (4). Contracts to support unusual or compelling needs; (5) Awards made to foreign vendors for work performed outside the United States, If it impractical to obtain CCR registration; (6) Micro-purchases that do not use the electronic funds transfer (EFT) method for payment and are not required to be reported; and (7) Expert witness and litigative consultants who refuse to register as a condition for providing their services.

- a. Check whether this is a change or creation of a new vendor code. If it is for a new vendor, an approved source document must be attached or the form will not be processed. Proper source documents are listed in the FFS Financial Handbook, section 5.4 Obligation Documents.
- b. Enter the name of the company/agency under contract or performing business with DEA
- c. An I.R.S. form W-9. Request for Taxpayer Identification Number and Certification, completed by the vendor must be attached for all US vendors unless they are a government entity. W-9 forms are not required for Foreign vendors.
- d. Remit to address of the vendor if different from the address on the W-9 form, otherwise put N/A.
- e. If the vendor is tax exempt a copy of the exempt certificate must be attached unless the vendor is a government entity. Also check if the vendor is a government entity or not.
- f. The city of the vendor's remit to address; otherwise put N/A.
- g. The state of the vendor's remit to address; otherwise put N/A.
- h. The zip code of the vendor's remit to address; otherwise put N/A.
- i. Name of the contact person at the vendor's place of business for DEA to contact.
- j. Fill in the phone number of the vendor's contact person.
- k. Enter the DEA Employee's name and phone number responsible for supervising this DEA vendor.
- 1. Print the name of the vendor's financial institution/bank.
- m. Print the city of the vendor's bank.
- n. Print the state of the vendor's bank.
- o. Print the zip code of the vendor's bank's address.
- p. Print the phone number of the vendor's bank.
- q. Enter the nine digit routing transit of the vendor's bank.
- r. Enter the account number in the vendor's bank for which the vendor wishes payments deposited.
- s. Enter the type of account for the associated account number you listed.
- T. Print the full name of the vendor record requester.
- u. The vendor record requester must sign their name using his/her official signature.
- v. Print the title of the vendor record requester.
- w. Enter the phone number of the vendor record requester,
- x. Enter the DEA office organization code of the vendor record requester.
- y. Enter the date on which the vendor record requester signed the form.

FORM DEA-1378 Instructions (03-04) Previous editions obsolete

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PAGE 01

# U.S. Department of Justice Drug Enforcement Administration Office of Chief Counsel

www.dea.gov

Washington, D.C. 20537

October 25, 2007

Honorable Mary Ellen Bittner DEA Office of Administrative Law Judges Washington, D.C. 20537

Re: In the Matter of McKesson Corporation, DEA Docket No. 06-66

To the Honorable Judge Bittner:

The Government requests that a subpocna be issued to compel the appearance and testimony of the following witness at Arlington, Virginia (estimated for October 30, 2007) and be tendered to the Government for appropriate service.

Michael Mapes 9323 Hallston Court Fairfax Station, Virginia 22039

Respectfully submitted,

Wayne Patrick

Counsel for the Government

cc: John A. Gilbert, Jr., Esq. F: (202) 737-9329





# United States Department of Justice

Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

October 25, 2007

Wayne Patrick, Esq.
Office of Chief Counsel
Drug Enforcement Administration
Washington, D.C. 20537

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

Dear Mr. Patrick:

On October 25, 2007, you filed a request for a subpoena in the above-referenced matter. A subpoena for the following individual is enclosed.

Michael Mapes 9323 Hallston Court Fairfax, Virginia 22039

If you have any questions or need additional information, please contact my law clerk, Thomas 'Skip' Mark, at (202) 307-8188.

Sincerely,

Mary Ellen Bittner

Administrative Law Judge

Mary Ellen Bethun

Enclosure

cc: John A. Gilbert, Jr., Esq. (w/o enclosure)

10/26/2007 12:20

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OFC OF CC (CCD-/CR)

PAGE 01/03

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov	> Canada	••••
•	OPTIONAL FORM 99 (7-80)	
	FAX TRANSMITTAL Tot pages F 3	~~,
John A. Gilbert, Jr.	OSPANSED BY BEEF PROPER	e.
Hyman, Phelps, and McNamara PC 700 Thirteenth Street, N.W. Suite 1200	FEX.* ZOZ-737-93 Z 9 FEX.*  NSH 7540-01-317-7388 5099-101 GENERAL BERVICES ADMINISTRATIO	Ñ

Dear Mr. Gilbert:

Washington, D.C. 20005

In furtherance of our settlement discussions, the Drug Enforcement Administration (DEA) has authorized me to extend the following offer to the McKesson Corporation (McKesson) to resolve certain pending and potential administrative and civil actions against McKesson. Although the specific language of any agreement must be put into a binding written agreement, the key terms of such a settlement from DEA's perspective are as follows:

- 1. McKesson must pay civil fines for failing to report suspicious orders in accordance with 21 C.F.R. § 1301.74(b) as follows:
  - A. In the Middle District of Florida, McKesson must pay \$12.8 million;
  - B. In the District of Maryland, McKesson must pay \$2.4 million; and
  - C. In the Southern District of Texas, McKesson must pay \$2.4 million.

Final approval from the appropriate United States Attorneys' Offices must be obtained prior to finalizing the proposed civil fine settlement. DEA fully supports settlement at the proposed levels and anticipates final approval from the United States Attorneys' Offices.

- 2. In the Eastern District of California, McKesson must pay \$280,000 for failing to report thefts and significant losses in accordance with 21 C.F.R. § 1301.74(c).
- 3. McKesson must enter a national Memorandum of Agreement (MOA) covering all registered distribution centers owned or operated by McKesson, including those that may be acquired or registered in the future. The MOA's key terms are as follows:
  - A. McKesson must agree to a suspension of its Schedule III hydrocodone codes in the Lakeland and Conroe distribution centers for a period of not less than six months. These drug codes will be restored upon McKesson's implementation of all other requirements set forth in the national MOA, and upon passing an inspection by DEA. If McKesson

10/25/2007 12:20

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PAGE 02/03

fails to implement all requirements of the MOA or fails to pass DEA's inspections, DEA will notify McKesson in writing of the deficiencies and will extend the suspensions.

- B. McKesson must agree to implement a system that reports to DEA via Electronic Data Interchange the distributions of all controlled substances and all ephedrine and pseudoephedrine products. Reports must be made to DEA within two business days of the distribution.
- C. McKesson must agree to inform DEA of all suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b), except that McKesson must make such reports to DEA Headquarters in a format that is mutually and reasonably agreed upon by the Parties.
- D. McKesson must acknowledge that any express or implied approval by DEA of a suspicious order reporting system that permits McKesson to provide a monthly "excessive purchase report" is rescinded, and that such a system does not comply with 21 C.F.R. § 1301.74(b).
- E. McKesson must agree that it will not fill a suspicious order unless and until a McKesson employee determines that, notwithstanding the suspicious nature of the order, the order is indeed for a legitimate purpose and not likely to be diverted.
- F. McKesson must agree to submit to inspections by DEA for the purpose of determining compliance with the MOA. Inspections will occur not sooner than 90 days after the execution of the MOA and not later than 150 days after the execution of the MOA. DEA will inspect the Lakeland, Florida and Conroe, Texas facilities, and up to six additional facilities. McKesson must agree to one additional inspection of its Lakeland and Conroe facilities after the hydrocodone drug codes are restored. These inspections shall occur within 180 days after the hydrocodone codes are restored. This provision shall in no way limit the authority of DEA to conduct inspections or engage in other authorized regulatory law enforcement activities at or with respect to any of McKesson's registered locations.
- G. McKesson must agree to review its past distributions of hydrocodone and alprazolam and conduct investigations of any current customers that have placed suspicious orders for hydrocodone and alprazolam within the preceding 24 months.
- H. DEA will agree that it will not pursue any administrative action against any McKesson distribution center for distributions of hydrocodone or alprazolam that occurred prior to the execution of the agreement.
- I. DEA will agree that it will not refer to any United States Attorney's Office a case in pursuit of a civil fine against any McKesson distribution center based upon distributions of hydrocodone or alprazolam that occurred prior to the execution of the agreement other

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PAGE 03/03

than the fines set forth in paragraph 1 above. Note that the fine in paragraph 2 is not based on distributions of hydrocodone or alprazolam.

If you believe that this letter does not comport with our discussion on October 25, 2007, please contact me. This offer shall remain effective until October 26, 2007 at 5:00 p.m. Eastern Daylight Time or unless withdrawn in writing by DEA.

Sincerely,

D. Linden Barber

Associate Chief Counsel

Diversion and Regulatory Litigation Section





Office of Chief Counsel <sup>1</sup> 8701 Morrisette Drive Springfield, VA 22152

www.dea.gov

November 1, 2007

Honorable Mary Ellen Bittner Office of Administrative Law Judges Washington, DC 20537

Re: In the Matter of McKesson Drug Company, DEA Docket No. 06-66

The parties request that the Office of Administrative Law Judges tender to the parties a copy of the official transcript taken in this matter on October 30-31, 2007 as soon as it is available. I have spoken with counsel for Respondent, and he joins in this request.

Respectfully.

Wayne Patrick

Attorney

Drug Enforcement Administration

Cc: John Gilbert, Jr., Esq. Hyman, Phelps & McNamara 700 Thirteenth Street, NW Washington DC 20005

P-00016\_00164

<sup>&</sup>lt;sup>1</sup> Please note new address for regular mail and express delivery mail to DEA HQS offices.





# United States Department of Justice

Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

November 7, 2007

John A. Gilbert, Jr., Esq. Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

### Dear Counsel:

As you know, the hearing in this proceeding will be held at the Drug Enforcement Administration's (DEA) headquarters. The Office of Security Programs requires a list of all individuals attending the hearing other than DEA employees.

Please notify this office of all persons attending the hearing by 4:00 p.m. eastern standard time on Tuesday, November 13, 2007. Please direct your response to the Hearing Clerk, Ms. Helen Farmer, and provide the individuals' full name and date of birth. Your prompt attention to this matter is greatly appreciated.

If you have any additional questions or concerns, please contact me at (202) 307-8188. Thank you for your cooperation.

Respectfully

Thomas 'Skip' Mark

Law Clerk to Mary Ellen Bittner

Administrative Law Judge

Wayne M. Patrick, Esq., Office of Chief Counsel Helen Farmer, Office of Administrative Law Judges

cc:





# United States Department of Justice

Drug Enforcement Administration Office of Administrative Law Judges Washington, D.C. 20537 (202) 307-8188

November 7, 2007

Wayne M. Patrick, Esq.
Office of Chief Counsel
Drug Enforcement Administration
Washington, D.C. 20537

John A. Gilbert, Jr., Esq. Hyman, Phelps & McNamara, P.C. 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005

Re: In the Matter of McKesson Corporation d/b/a McKesson Drug Company
Docket No. 06-66

Dear Counsel:

At Judge Bittner's direction, I am writing to advise you that the hearing scheduled to begin at 9:30 a.m. on November 27, 2007, will be held in the hearing room at the Drug Enforcement Administration's headquarters, 600 Army Navy Drive, Arlington, Virginia 22202. This session of the hearing is scheduled to last for three days.

You are reminded to meet the law clerk at 9:00 a.m. on the first day of the hearing to have exhibits marked. Please bring an extra set of exhibits for the judge, and make certain that witnesses are available to testify without delay.

If you have any additional questions or concerns, please contact me at (202) 307-8188.

Respectfully,

Thomas 'Skip' Mark

Law Clerk to Mary Ellen Bittner

Administrative Law Judge

LAW OFFICES

5603.013.01

# HYMAN, PHELPS & MCNAMARA, P.C.

JOHN A. GILBERT, JR.

700 THIRTEENTH STREET, N.W.
SUITE 1200
WASHINGTON, C. C. 20005-5929
12021 737-5800
FACSIMILE
12021 737-9329
WWW.hpm.com

Direct Dial (202) 737-4293

November 19, 2007

# BY FACSIMILE/CONFIRMATION COPY BY MAIL

Linden Barber, Esq.
Chief, Regulatory Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army/Navy Drive
Arlington, Virginia 22202

Dear Mr. Barber:

This will confirm our telephone conversation on Friday, November 16, 2007, on the proposed settlement of the pending Drug Enforcement Administration (DEA) administrative and civil actions against several McKesson Corporation (McKesson) facilities. McKesson has agreed to the government's demand to pay a civil penalty in the amount of \$13.25 million and enter a settlement agreement with DEA. This offer is contingent on parties finalizing the settlement agreement.

The payment of the fine and settlement agreement will involve a global settlement covering all McKesson facilities, including but not limited to, the matters identified at McKesson's facilities in Lakeland, Florida; Landover, Maryland; Conroe, Texas; West Sacramento, California; and the potential allegation against one of our facilities you mentioned in our telephone conversation.

2803 MAIN STREET SUITE 780 IRVINE, CALIFORNIA 92814 IS481 553-7400 FAX: IS481 553-7433 4819 EMPEROR SCULEVARO SUITE 400 DURHAM NORTH CAROLINA 27703 SHOL 313 4751 FAX 18181 313 4751 Linden Barber, Esq. November 19, 2007 Page 2 HYMAN, PHELPS & MCNAMARA, P.C.

I also understand that the parties will move the Administrative Law Judge (ALJ) to stay the administrative hearing currently pending before DEA, DEA Docket No. 06-66, with the intent to terminate the proceedings upon entering a final settlement agreement.

Please let me know as soon as possible if you disagree with any part of this summary.

ノルー

ohn A. Gilbe¦rt, Jr

cc: Ina Trugman, McKesson Corporation





LAW OFFICES

# HYMAN, PHELPS 8 MCNAMARA, P.C.

JAMES R. PHELPS
PAUL M. HYMAN
ROBERT A. DORMER
STEPHEN H. MCNAMARA
ROGER C. THIES
THOMAS SCARLETT
JEFFREY N. GIBBS
BRIAN J. DONATO
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JOHN R. FLEDER
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CHRISTINE P. BUMP
BRIAN J. WESOLOSKI
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RÉTIE VAN LAACK\*
CARMELINA G. ALLIS\*

ANOT ADMITTED IN DO

CHERYLE GRAHAM MOLFCP

# FACSIMILE TRANSMITTAL SHEET

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Tel. No.: (202) 737-5600

FROM:

John Gilbert

DATE:

November 19, 2007

TO:

Linden Barber

FAX NO.:

(202) 307-4946

Fax No.: (202) 737-9329

NO. OF PAGES (including this page):

2003 main Street Suite 700 Irvine, California 92814 19481 553-7400 Fäx: 19481 553-7433 4819 Emperor Bouleyard Suite 400 Durham, North Carolina 27703 ISBN 313-4750 Fax: ISBN 313-4751



Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 08-14

### ORDER

On November 20, 2007, counsel for Respondent filed a request for hearing in the above-captioned matter and, in accordance with a November 19, 2007 telephonic conference with counsel for both parties, requested an indefinite stay of the proceedings pending a settlement of this matter.

In light of the position of the parties to this matter, Respondent's request for a stay is granted, and it is hereby

ORDERED that the proceedings in this matter will remain stayed until March 10, 2008. Counsel for both parties shall participate in a status conference call at 10:00 a.m. on December 17, 2007, apprising me of the progress of settlement negotiations.

Dated: November 23, 2007

Administrative Law Judge

### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 23, 2007, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Law Clerk to Mary Ellen Bittner Administrative Law Judge

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

#### ORDER

On November 19, 2007, I held a telephonic conference with counsel for both parties to the above-captioned matter. In that conference, counsel advised me that the parties were currently engaged in settlement negotiations, and requested a stay of the proceedings so that they can pursue a settlement.

In light of the position of the parties the parties' request for a stay is granted, and it is hereby

ORDERED that the hearing scheduled for November 27-29, 2007, is cancelled. and it is further

ORDERED that the proceedings in this matter will remain stayed until March 10, 2008. Counsel for both parties shall participate in a status conference call at 10:00 a.m. on December 17, 2007, apprising me of the progress of settlement negotiations.

Dated: November 23, 2007

Administrative Law Judge

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PAGE 01/01

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

NOV 1 9 200

John A. Gilbert, Jr.
Hyman, Phelps, and McNamara PC
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005

Dear Mr. Gilbert:

FAX TRANSMITTAL | s of peges to |

TO JOHN GILBERT | From ZINDEN BARBE
Dept. Agency | Phone s

Fax s 737-9329 | Fax s

NSN 7890-31-317-7388 | 8098-105 | GENERAL REPLACES ADMINISTRATIV

I received your letter dated November 19, 2007. I agree that the Drug Enforcement Administration (DEA) and McKesson Corporation (McKesson) should jointly seek a stay of the administrative proceedings involving McKesson's Lakeland, Florida Distribution Center while we attempt to finalize the tentative agreement that we have reached.

I generally agree with the propositions set forth in your letter. However, I note that the new matter involving a fifth McKesson Distribution Center that I discussed with you on November 16, 2007, is not necessarily included in the terms of the proposed settlement. I am working with the DEA Field Division that is investigating the matter to determine the nature and scope of DEA's concerns. I have received information that the preliminary investigation revealed concerns about McKesson's distribution of a wide variety of controlled substances including hydrocodone, methadone, and oxycodone. The distributions were made to an entity that engaged in diversion unrelated to Internet diversion schemes or purported "pain management" clinics and pharmacies. As I indicated in our telephone conversation, DEA cannot commit to resolving this case as part of the global settlement without obtaining additional information.

Also, your letter did not refer to the additional demand that DEA made in its counter-offer requiring McKesson to forego distribution of alprazolam from it Conroe, Texas and Lakeland, Florida Distribution Centers. If McKesson understands the terms of DEA's offer and believes that a settlement can be reached, a stay of the proceedings is appropriate. I understand that the uncertainty regarding the fifth McKesson facility must be resolved before the parties can finalize a settlement.

Sincerely,

D. Linden Barber

Associate Chief Counsel

Lidal

Diversion and Regulatory Litigation Section

P-00016 00173

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket No. 06-66

### MEMORANDUM TO COUNSEL

On December 17, 2007, I held a telephonic conference with counsel for both parties to discuss the progress of settlement negotiations in the above-captioned matter. In that conference, counsel advised me that the parties were still engaged in settlement negotiations, but had reached an agreement in principle. In light of the progress of negotiations, I scheduled a second telephonic status conference for January 14, 2008 at 10:00 a.m. eastern standard time, unless the parties reach a settlement prior to this date.

Dated: December 17, 2007

Mary Ellen Bittner

Administrative Law Judge

P-00016 00174

# CERTIFICATE OF SERVICE

This is to certify that the undersigned, on December 17, 2007, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne M. Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Law Clerk to Mary Ellen Bittner Administrative Law Judge





# HYMAN, PHELPS & MCNAMARA, P.C.

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# **FACSIMILE TRANSMITTAL SHEET**

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Tel. No.: (202) 737-5600

Fax No.: (202) 737-9329

FROM:

John Gilbert

DATE:

March 7, 2008

TO:

Linden Barber

FAX NO .:

(202) 307-4946

NO. OF PAGES (including this page):

2603 Main Street Suite 760 Irvine. California Bebig 19481 883-7400 Fax. 19481 883-7433 4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
ISISI 313-4750
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LAW OFFICES

# HYMAN, PHELPS & MCNAMARA, P.C.

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# FACSIMILE TRANSMITTAL SHEET

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Tel. No.: (202) 737-5600 Fax No.: (202) 737-9329

FROM:

John Gilbert

DATE:

March 7, 2008

TO:

Honorable Mary Ellen Bittner

FAX NO.:

(202) 307-8198

Wayne Patrick

(202) 307-4946

NO. OF PAGES (including this page):

2003 MAIN STREET SUITE 700 IRVINE, CALIFORNIA 92814 19401 883-7400 FAX: 19401 883-7433 4819 EMPEROR BOULEVARD SUITE 400 DURHAM, NORTH CAROLINA 27703 IDIGI 313-4780 FAX: IBIBI 313-4781



# U. S. Department of Justice Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

MAY 0120m

Mr. John A. Gilbert, Jr. Hyman, Phelps & McNamara, P.C. 7100 Thirteenth Street N.W. Washington, D.C. 20005-5929

Dear Mr. Gilbert:

I am writing to confirm our telephone conversation of May 1, 2008. In order to finalize the Settlement Agreement between the United States and McKesson Corporation ("McKesson"), we agreed to make (and I made) the following changes to the Settlement Agreement ("Agreement"):

- 1. On the first line of the first paragraph of the Agreement, I inserted "30<sup>th</sup>" in to the blank to indicate that the Parties entered into the Agreement on April 30, 2008, when Mr. Donald Walker was the last representative of a Party to sign the Agreement.
- 2. In paragraph 17, I replaced "April" with "May" to reflect that administrative Memorandum of Agreement ("MOA") between the Drug Enforcement Administration ("DEA") and McKesson will be finalized in May rather than April. We further agree that upon DEA's execution of the MOA, I will insert the date of the MOA into the blank in paragraph 17.
- 3. In paragraph 22, I struck one occurrence of the word "this" as the word erroneously appeared twice in succession.

In order to finalize the MOA, we agreed to make (and I made) the following changes to the MOA:

- 1. On the second line of the first paragraph of the MOA, I replaced "April" with "May" to reflect that MOA between DEA and McKesson will be finalized in May rather than April.
- 2. On the copy of page 10 that has been executed by McKesson's representatives, I replaced "April" with "May" in the datelines beneath the signature blocks for DEA's representatives.

By my signature on this letter, I warrant that I am authorized by the six United States Attorney's Offices who executed the Agreement to make the changes that are set forth above to the Agreement. I further warrant that I am authorized by DEA to make the changes that are set forth above to the MOA. The modified Agreement and MOA will be the final and binding Agreement and MOA.

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In order to affix the signature pages to Agreement and MOA as modified in accordance with this letter, I require your consent and representation that you are authorized by your client to make these technical modifications. Please counter-sign this letter and return to me by email at your earliest convenience.

Sincerely.

D. Linden Barber

Associate Chief Counsel

Diversion & Regulatory Litigation Section

On behalf of McKesson, I consent to the technical changes described in the letter above that are being made to the Agreement and the MOA to which McKesson is a party. I am authorized by McKesson to consent to these changes. The modified Agreement and MOA will be the final and binding Agreement and MOA.

John A. Gilbertl Jr.

Hyman Phelps & McNamara, P.C. Counsel to McKesson Corporation

Dated: May \_ / , 2008

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company Docket Nos. 06-66 08-14

# ORDER

On March 7, 2008, counsel for Respondent filed a Consent Motion to Stay Administrative Hearings and Proceedings in the above-captioned matters. The Government and Respondent, through counsel, move to stay the administrative hearing in Docket No. 06-66 and to stay further proceedings in Docket No. 08-14 so that they may finalize their settlement agreement in both matters.

In light of the position of the parties the parties' request for a stay is granted, and it is hereby

ORDERED that the hearing scheduled for March 10-12, 2008, is cancelled, and it is further

ORDERED that the proceedings in both of the above-captioned matters will remain stayed indefinitely. If the parties have not settled these matters prior to April 7, 2008, my attorney advisor will contact counsel for the respective parties to schedule a status conference.

Dated: March 7, 2008

By the direction of Mary Ellen Bittner

Administrative Law Judge

# CERTIFICATE OF SERVICE

This is to certify that the undersigned, on March 7, 2008, caused copies of the foregoing to be faxed and delivered via interoffice mail to counsel for the Government, Wayne M, Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and copies to be faxed and mailed, postage paid, to counsel for Respondent, John A, Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Attorney Advisor to Mary Ellen Bittner

Home EHL

Administrative Law Judge

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

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In The Matter of	)	
	)	
McKesson Corporation	)	Docket Nos. 06-66 and
d/b/a McKesson Drug Company	)	08-14
	)	

# CONSENT MOTION TO STAY ADMINISTRATIVE HEARING AND PROCEEDINGS

McKesson Corporation (Respondent), by and through the undersigned counsel, files this Consent Motion to indefinitely stay the administrative hearing in Docket No. 06-66 and stay further proceedings in Docket No. 08-14.

In support of the Consent Motion, McKesson asserts the following:

- 1. The Government and Respondent have reached an agreement in principle to resolve both of the above captioned matters. The parties are continuing to negotiate the terms of the settlement in both matters.
- 2. The Government and Respondent have discussed this matter and both parties mutually desire to request an indefinite stay of the matters to allow time to finalize the settlement agreement in these matters.
- 3. The Government and Respondent request that the ALJ schedule a telephonic status conference within 30 days.

Wherefore, the Government and Respondent request that the Administrative Law Judge cancel the hearing in Docket No. 06-66 scheduled to commence on March 10, 2008, and stay further proceedings in Docket Nos. 06-66 and 08-14.

Respectfully submitted,

John A. Gilbert, fr.

Hyman, Phelps & McNamara PC 700 Thirteenth Street, N.W. Washington, D.C. 20005 (202) 737-5600

(202) 737-3600 (202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: March 7, 2008

### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on March 7, 2008, caused a copy of the foregoing to be delivered by facsimile with a confirmation copy by hand delivery to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be delivered by facsimile and regular mail to:

Wayne Patrick
Diversion and Regulatory Litigation Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, Virginia 22202

D. Linden Barber Chief, Regulatory Section Office of Chief Counsel Drug Enforcement Administration 600 Army/Navy Drive Arlington, Virginia 22202

Kathleen McKinley

Time

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Tel line : 2027379329

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HYMAN, PHEIPS & MCNAMARA, P.C.

# SETTLEMENT AND RELEASE AGREEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2<sup>nd</sup> day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

#### APPLICABILITY

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

#### BACKGROUND

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Denver, Colorado distribution center (the "Denver Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson has failed to report suspicious orders of controlled substances and to report thefts or significant losses of controlled substances as more fully set forth in Appendix B, Paragraph 8 as required by 21 C.F.R. 1301.74(b); and

WHEREAS, McKesson is registered with DEA at 39 facilities as distributors of Schedule II-V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention Control Act of 1970, Title 21 U.S.C. § 801 et seq., ("CSA" or "the Act"); and

WHEREAS, McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports; and

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the Orders and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

# I. General

- 1. <u>Intention of Parties to Effect Settlement</u>. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.
- 2. No Admission or Concession. This Agreement is neither an admission by McKesson of liability or of any allegations made by DEA in the Orders and investigations, nor a concession by DEA that its allegations in the Orders and investigations are not well-founded.
- 3. <u>Covered Conduct</u>. For purposes of this Agreement, "Covered Conduct" shall mean the following:
  - (i) the conduct alleged in the Orders;

- (ii) the alleged failure of McKesson to maintain adequate controls against the diversion of controlled substances, on or prior to December 31, 2007, at all distribution facilities operated, owned, or controlled by it;
- (iii) the conduct described in Appendix B, Paragraph 8 to this Agreement; and
- (iv) the alleged failure of McKesson to detect and report suspicious orders of the controlled substances as required by 21 C.F.R. § 1301.74(b) on or before December 31, 2007.
- 4. <u>DEA Headquarters</u>. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.
- 5. McKesson Representative. For purposes of this Agreement, the McKesson Representative shall be the Senior Vice President, Distribution Operations or the Vice President, Regulatory Affairs.

# II. Terms and Conditions

# 1. Obligations of McKesson.

- (a) McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions. McKesson acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.
- (b) Within five (5) business days following the date of each controlled substance transaction, McKesson shall provide DEA Headquarters with a report of all controlled substance transactions through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and thus does not contain any adjustments or corrections that would normally be part of McKesson's reconciliation of its business records. The Parties agree that the report does not

otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). McKesson shall begin transmitting this information no later than 120 days after the Parties have mutually agreed upon a format. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

- (c) McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, McKesson shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.
- (d) McKesson agrees to a temporary suspension of its authority to distribute drugs containing the drug codes for Schedule III hydrocodone combination products and alprazolam, that is, DEA drug codes 9805, 9806 and 2882 with respect to the DEA registrations for its Lakeland Facility and its Conroe Facility, except for sales to the accounts as listed in Appendix C. The temporary suspension shall terminate in accordance with subsection II.2(g) unless sooner terminated by the Parties in writing pursuant to the terms of this Agreement.
- (e) McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to McKesson's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).
- (f) McKesson agrees that within 120 days of the Effective Date of this Agreement it will review distributions of hydrocodone and alprazolam for the 24-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of hydrocodone and alprazolam exceeded the thresholds established in its compliance program. McKesson shall conduct an investigation and take appropriate action as required by this Agreement, DEA regulations and other procedures established under McKesson's compliance program including its Controlled Substance Monitoring Program (CSMP).
- (g) McKesson's policy and procedure is to cooperate with the government in any investigation. McKesson agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any

pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party.

- (h) McKesson agrees to pay civil penalties to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of \$13,250,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and for failing to report thefts or significant losses of controlled substances. Payment of said civil penalties shall be made by McKesson in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix B, Paragraph 13. McKesson agrees to execute the Settlement Agreement at Appendix B simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said civil penalties within 30 days of the Effective Date of this Agreement.
- (i) Any material breach by any McKesson facility of subsections II.1(a)-(h) of this Agreement by McKesson after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of McKesson's DEA certificate(s) of registration for that facility.

### 2. Obligations of DEA.

- (a) At McKesson's request, DEA shall continue to provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members at McKesson trade shows and through written materials. The frequency and content of such training shall be at DEA's sole discretion.
- (b) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II.1(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.
- (c) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to this customer.
- (d) DEA agrees that any request made by DEA or any of its employees that McKesson continue to sell controlled substances to customers for an order that McKesson has determined to be suspicious shall be made in writing to the designated McKesson Representative.

- (e) Within 150 days of the Effective Date of this Agreement, but not earlier than 90 days after the Effective Date of this Agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program ("Compliance Reviews") at up to eight distribution centers of McKesson, consisting of the Lakeland Facility; the Landover Facility; the Conroe Facility; and five other McKesson distribution centers selected by DEA. DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify McKesson no less than 48 hours prior to commencing a Compliance Review at a distribution center. DEA shall issue a Notice of Inspection to McKesson upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the Compliance Review.
- (f) The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to McKesson on or before 165 days from the Effective Date of Agreement, stating that McKesson failed to meet any of the requirements in either subsections II.2(f)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with McKesson within 48 hours regarding such a finding. DEA shall consider remedial measures that McKesson has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.
- (g) Upon the completion of the Compliance Reviews and within 180 days of the Effective Date of this Agreement, DEA will restore the drug codes 9805, 9806 and 2882 to the DEA registrations for the Lakeland and Conroe Facilities. In the event that McKesson has not satisfied DEA in regard to the Compliance Reviews within 180 days of the Effective Date of this Agreement and DEA issues a Show Cause against either of the Lakeland or Conroe Facilities, McKesson agrees to a new period of suspension of the drugs codes at such facility until the matter is resolved by mutual agreement of the Parties or a final decision by the DEA Deputy Administrator. Notwithstanding, nothing in this Agreement shall prevent the Parties from agreeing to an extension or shortening of the suspension period for these drugs codes at the Lakeland and Conroe Facilities at any time during the course of this Agreement. DEA shall not be prevented from taking any action that would otherwise be available to the agency to pursue a new period of suspension of the drug codes at these facilities.

- (h) DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.
- (i) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement; all actions taken by McKesson pursuant to this Agreement; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility and at other McKesson facilities.
- (j) DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to December 31, 2007, which may allege that McKesson failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by McKesson to DEA on or before December 31, 2007 for indications that McKesson may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix B, Paragraph 8) occurring before December 31, 2007, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.
- 3. <u>Joint Obligations of the Parties</u>. McKesson and DEA agree that upon the execution of this Agreement, DEA and McKesson shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Lakeland Facility and Landover Facility.
- 4. Release by DEA. (i) In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:
  - (i) Release McKesson from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders; and
  - (ii) Refrain from filing any administrative claims against McKesson within DEA's enforcement authority under21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of December 31, 2007, and the review of the reports and records McKesson submitted to DEA prior to December 31, 2007.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement

agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that McKesson's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

- 5. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:
- (a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or
  - (c) Any liability based upon such obligations as are created by this Agreement.

## III. Miscellaneous

- 1. <u>Binding on Successors</u>. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.
- 2. <u>Costs</u>. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
- 4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

- 5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) five (5) business days after the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.
- 6. <u>Disclosure</u>. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction. However, the Parties agree to provide each other with advance notice the day before or as soon as possible once a decision has been made to issue any public statement or press release related to this Agreement. The Parties shall provide copies of any press release no later than two hours before issuing the press release. This paragraph does not apply to any press release or public statement issued by the Department of Justice or any United States Attorney's Office. This paragraph shall remain in effect for sixty (60) days, commencing with the Effective Date of the Agreement.
- 7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
- 8. <u>Authorizations</u>. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
- 9. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the McKesson distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

MCKESSON CORPORATION

lob th. Hammergren

President

McKesson Corporation

Dated: April 28, 2008

Bv

Donald G. Walker Senior Vice President McKesson Corporation

Dated: April 30, 2008

THE UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT/ADM/NISTRATION

Bw

Michele M. Ldon/air Acting Administrator

Drug Enforcement Administration

Dated: May **2**, 2008

Wendy H Goggin

Chief Counsel

Drug Enforcement Administration

Dated: May /\_\_\_, 2008

# Appendix A

# McKesson Distribution Center DEA Registered Facilities

Location	DEA Registration #
Carol Stream, IL	RM0220599
Methuen, MA	PM0020850
West Seneca, NY	PM0003094
Everett, WA	PM0150538
Anchorage, AK	RM0227430
Aurora, CO	PM0018425
Livonia, MI	PM0030849
Honolulu, HI	PM0001014
Santa Fe Springs, CA	PF0000012
Duluth, GA	PR0040357
Memphis, TN	PM0001951
Washington Ct. House, OH	RM0220688
Oklahoma City, OK	RM0138328
La Vista, NE	PM0038693
Tolleson, AZ	PM0021131
Wilsonville, OR	PM0022929
La Crosse, WI	RM0220537
Delran, NJ	RM0173055
Salt Lake City, UT	PM0023046
West Sacramento, CA	PM0021535
O'Fallon, MO	PM0037374
Memphis, TN	RM0207286
Lakeland, FL	PM0000771
New Castle, PA	RM0258601
Landover, MD	PD0029567
Aberdeen, SD	RM0335869
Conroe, TX	RM0328408
McCalla, AL	RM0336950
Little Canada, MN	PM0036334
Cape Girardeau, MO	RM0337534
Rocky Hill, CT	PR0104593
Aurora, CO	RM0354958

Appendix B

# SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this \_\_\_\_\_\_ day of April, 2008, by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of Maryland, Middle Florida, Southern Texas, Colorado, Utah and Eastern California ("United States") and McKesson Corporation including facilities doing business as McKesson Pharmaceuticals and McKesson Drug Company, ("McKesson") and collectively referred to as "the Parties."

# RECITALS

- 1. McKesson is a Delaware corporation and is headquartered in San Francisco, California. Among other things, McKesson is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, McKesson operates numerous distribution facilities in the United States, including six facilities more fully described in Attachment A to this Agreement ("the Six Facilities").
- 2. As more fully described in Attachment A, McKesson holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from these facilities including the Six Facilities.
- 3. McKesson is required to operate the Six Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("the CSA").
- 4. Each of the Six Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective

jurisdictions as stated in Paragraph 8.

- 5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.
- 6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. See 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).
- 7. Methadone, Hydrocodone, Phentermine, Fentanyl and Oxycodone are medications whose manufacture, distribution, sale and possession are regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).
- 8. The "Covered Conduct" shall mean the following alleged conduct:
  - A. Within the District of Maryland: From January 2005 through October 2006, McKesson-Landover sold approximately 3 million dosage units of hydrocodone to NewCare Pharmacy in Baltimore, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). Further, from August 2006 to February 2007, McKesson-Landover sold large quantities of phentermine based products to Smeeta Pharmacy in Highland, Maryland and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
  - B. Within the Middle District of Florida: In October 2005, McKesson-Lakeland sold approximately 2.1 million dosage units of hydrocodone to seven pharmacies in the Tampa area (Trelles Pharmacy, BiWise Drugs, Universal RX, United Prescription Service, Accumed Rx Medipharm RX and Avee Pharmacy) and falled to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
  - C. <u>Within the Southern District of Texas:</u> From February to September 2007, McKesson-Conroe sold approximately 2.6 million dosage units of hydrocodone to Mercury Drive Pharmacy and Maswoswe's Alternative Pharmacy and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

- D. Within the District of Colorado: From September 2005 through November 2007, McKesson-Aurora sold large quantities of hydrocodone to three Colorado pharmacies (Brighton Pharmacy in Brighton, Colorado; Western States Pharmacy in Brighton, Colorado; and St. Vrain's Pharmacy in Lyons, Colorado), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
- E. <u>Within the District of Utah:</u> From January 2005 through October 2007, McKesson-Salt Lake City sold approximately 824,000 dosage units of hydrocodone, Oxycodone, Fentanyl and Methadone to the Blackfeet Clinic in Browning, Montana, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
- F. Within the Eastern District of California: From October 2007 through June 2007, McKesson-West Sacramento suffered the theft or significant loss of controlled substances on twenty-eight separate occasions, and failed to timely submit required theft and loss reports to DEA, in violation of 21 C.F.R. §§ 1301.74(c) and 1301.76(b), and 21 U.S.C. § 842(a)(5).
- 9. By entering into this Agreement, McKesson does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing. McKesson explicitly denies any allegations of violations of the CSA or DEA regulations and represents that the company has defenses to the violations alleged by the government.
- 10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)), authorized the imposition of a civil penalty of up to \$25,000 for each violation of the Section, except that violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to \$10,000 for each violation.
- 11. To avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against McKesson under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by McKesson nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

# TERMS AND CONDITIONS

- 13. McKesson shall pay to the United States the sum of Thirteen Million, Two Hundred Fifty Thousand Dollars (\$13,250,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:
  - A. For Conduct Alleged to have Occurred within the District of Maryland: McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Maryland, pursuant to instructions provided by the United States.
  - B. For Conduct Alleged to have Occurred within the Middle District of Florida; McKesson shall pay the sum of Seven Million Four Hundred Fifty-Six Thousand Dollars (\$7,456,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.
  - C. For Conduct Alleged to have Occurred within the Southern District of Texas: McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.
  - D. <u>For Conduct Alleged to have Occurred within the District of Colorado:</u> McKesson shall pay the sum of One Million Dollars (\$1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.
  - E. For Conduct Alleged to have Occurred within the District of Utah: McKesson shall pay the sum of Five Hundred Forty-Four Thousand Dollars (\$544,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Utah, pursuant to instructions provided by the United States.
  - F. For Conduct Alleged to have Occurred within the Eastern District of California: McKesson shall pay the sum of Two Hundred Fifty Thousand Dollars (\$250,000). Payment shall be by electronic funds transfer to the United States Attorney's Office,

Eastern District of California, pursuant to instructions provided by the United States.

- 14. In consideration of the undertakings by McKesson, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842(c)(1) against McKesson, its officers, directors, and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.
- 15. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.
- 16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:
  - A. Any potential criminal liability;
  - B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);
  - C. Any administrative liability, including mandatory exclusion from any federal programs;
  - D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and
  - E. Any claims based on such obligations as are created by this agreement.
- 17. McKesson acknowledges that each of its DEA registered facilities is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken good-faith actions to detect and prevent

diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA dated May \_\_\_\_\_, 2008.

- 18. McKesson agrees that any and all costs it has or will incur in connection with this matter--including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action—shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.
- 19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.
- 20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between McKesson and an Office of the United States Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal judicial district of the Office with whom the dispute arose, and to the extent that state law applies to the dispute, the law of the State within the jurisdictional district shall apply. If a dispute arises under this Agreement between McKesson and more than one of the United States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie in the District of Maryland and to the extent that state law applies to the dispute, the law of Maryland shall apply.
- 21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.
- 22. This Agreement constitutes the entire agreement between the Parties and cannot be amended except in writing and when signed by all the Parties to this Agreement.

- 23. McKesson acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.
- 24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.
- 25. This Agreement shall be effective on the date of signing by all the Parties, It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

On Behalf of McKesson Corporation
One Post Street

San Francisco, California 94104

John H. Hammergren

President

By:

Dated: Apr. / 28 . 2008

John A. Gilbert Jr.

Hyman, Phelps & McNamara, P.C.

Counsel to McKesson Corporation

Dated: <u>/かん/ ひ</u> 2008

Rv:

Donald G. Walker Senior Vice President

Dated: <u>Apr. / 30</u>, 2008

On Behalf of the United States

ROD J. ROSENSTEIN United States Attomey

District of Meryland

Michael A. OlPiatro Assistant United States Attorney

Dated: April 21/2008

Dated; April 29, 2008

ROBERT E. ONEILL United States Attorney Middle District of Florids

Assistant United States Attorney

Dated: April 21, 2008

DONALD J. DøGABRIËLLE United States Allomey Southern District of Texas

Assistant United States Attorney

Dated: April 2008

TROY A. BID United States Attorney D'airict of Colorado

Amanda Rocque Azsistant United States Attorney

Daled: April 29, 2008

BRETT L. TOLMAN United States Attorney

Olatrica of Utahi

Eric A. Overby Assistant United States Altorney McGREGOR W. SCOTT United States Altomay Eastern District of California

Assistant United States Attorney

Oslad: April <u>29</u>, 2008

### ATTACHMENT A

# (Six McKesson Facilities Referenced in Paragraph 1 of this Agreement)

- 1. 7721 Polk Street in Landover Maryland ("McKesson-Landover"), located within the District of Maryland and operating under DEA registration number PD0029567;
- 2. 1515 West Bella Vista Street in Lakeland Florida ("McKesson-Lakeland"), located within the Middle District of Florida and operating under DEA registration number PM 0000771:
- 3. 3301 Pollock Drive in Conroe Texas ("McKesson-Conroe"), located within the Southern District of Texas and operating under DEA registration number RM 0328408;
- 4. 14500 East 39<sup>th</sup> Avenue in Aurora Colorado ("McKesson-Aurora"), located within the District of Colorado and operating under DEA registration number PM 0018425;
- 5. 1900 South 4490 West in Salt Lake City Utah ("McKesson-Salt Lake City"), located within District of Utah and operating under DEA registration number PM0023046; and
- 6. 3775 Seaport Boulevard in West Sacramento California ("McKesson-West Sacramento"), located within the Eastern District of California and operating under DEA registration number PM 0021535.

# Appendix C - Sales Accounts at Lakeland and Conroe Facilities authroized by DEA as an exception to Paragraph II.1(d). (Lakeland DC Code = 195/Conroe Code = 115)

Account Name	DC DEA	Addross	City	St	Ζίρ
CENTRAL TX VA-SPD TEMPLE	115 AB4451124	1901 SOUTH FIRST STRUCT	TEMPLE:	TX	76504
VA MED CTR CII PINEVILLE	115 AD3351070	2495 SHREVEPORT HWY	PINEVILLE	LA	71360
PCI SŁAGOVILLI:	115 AF2404527	2113 NORTH HIGHWAY 175	SEAGOVILLE	TX	75159
FCI MIAMI	195 AF6804733	15801 SW 137111 AVENUE	MIAMI	FL.	33177
I'CI IJASTROI'	115 AFX942650	1341 HIGHWAY 95 NORTH	BASTROP	TX	78602
USPHS HOSPITAL UNIT-FCI	195 AK4351982	FED CORVSOL CAPITAL CRINE	TALLAHASSEE	ľ.	32301
US PUBLIC HEALTH SERVICE	195 AU1434911	18201 SW 12 STREET	MAMI	121	33194
VA OP CLINIC PHARMACY	195 AV1230313	5599 N DIXIE HIGHWAY	OAKLAND PARK	F1.	33334
VA LAKE CITY OUTPATIENT	195 AV4277845	619 S MARION STREET	LAKE CITY	11.	32025
VA MEDICAL CENTEMINIPAT	195 AV4345559	1201 NW 16TH ST	MIAMI	M.,	33125
VA MEDICAL CENTER OF PRICY	115 AV4515790	2002 HOLCOMBE BLVD	HOUSTON	TX.	77030
VA MEDICAL CENTER-CII	115 AV4515815	510 EAST STONER AVE	SHREVERORT	LA	71101
VA MED CIR GAINESVILLE IP	195 AV4671372	1601 SW ARCHER ROAD	GAINESVILLE	11.	32608
CHNTRAL, TX VETS-CONT WACO	115 AV4718714	4800 MEMORIAL DRIVE	WACO	TX	76711
VA OUTPATIENT CLINK	195 AV5214488	1833 BOULEVARD	JACKSONVILLE	87I	32206
VA MEDICAL CENTER I/P	195 AV5307889	10000 BAY PINES BLVD	SAINT PETERSBURG	8×8.	33708
VA MEDICAL CTR-KERRVILLE	115 AV5318856	3600 MEMORIAL DRIVE	KERRVILLE	TX	7802X
VA MED CT IP-AUDIE MURPHY	115 AV5546936	7400 MERTON MINTER BLVD	SAN ANTONIO	TX	78229
VA MC I/PO/P NEW ORLEANS	115 AV6767719	1601 PERDIDO ST/RM#1F157	NEW ORLEANS	LA	70112
VA OIP CLINIC BEAUMONT	115 AV7507164	3420 VITTERAN CIRCLE	BEAUMONT	T.X	77707
VA OUTPATIENT CLIN ARMMS	195 AV8635469	3033 WINKLER AVE HIT	FORT MYERS	, 00 v	33916
VA OUTPATIENT CLINIC	115 AV9426760	7968 ESSEN PARK AVE	BATON ROUGE.	LA	70809
ALA-COUSHATTA INDIAN IIIS	115 BA7647502	129 DAYCARE KOAD	LIVINGSTON	1.7.	77351
FEDERAL PRISON CAMP PENSC	195 1101595911	FED PRISON CAMP PENSCOLA	PENSACOLA		32509
MICCOSUKEE HETH CIR HIS	145 13133449518	MILE MARKER 70, US HWY 41	MIANII	PL.	33144
COUSHATTA HET DEPART HIS	115 BC6820383	PO BOX 519 2003 CC BEL RO	ELTON	LA	70532
DEPT OF VET AFFAIRS MED	195 BD2256990	10 CALLE CASIA	SANJUAN	$p_{\mathcal{K}}$	921
VA MEDICAL CENTER	195 HD2669995	7305 NORTH MILITARY TRAIL	WEST PALM BEACH	FL.	33410
VA OUTPATIENT CLINIC	195 BD4632015	5201 RAYMOND STREET	ORLANDO	I.L	32803
VETS NURSING HM/FL SVII2	195 8105967180	1920 MASON AVENUE	DAYTONA BEACH	FL	32117
HALDOMERO LOPEZ MEM SVIIZ	195 BD6136534	6919 PARKWAY BLVD	LAND O LAKES	1.	34639
PED PRISON CMP BRYAN	115 BF1742332	LIOO URSULINE	BRYAN	TX	77803
HED DETENTION ONT OAKDALE	115 81/2225589	POB BOX 5060 II WHATLEY RD	OAKDALE	LA	71463
ICI TIIREE RIVERS	115 13172295017	PO BOX 4000 HWY 72 WEST	THREE RIVERS	TX	78071
FED DETENTION ONT MIAMI	195 111/3780219	33 NE 4TH STREET	MIAMI	FL	33132
FED CORR CMP COLEMAN	195 BF4461783	SI I NE SATH TERRACE	COLUMAN	11.	33521

# Appendix C - Sales Accounts at Lakeland and Conroe Facilities authroized by DEA as an exception to Paragraph II.1(d). (Lakeland DC Code = 195/Conroe Code = 115)

FED DETENTION CTR HOUSTON	115 BF6451506	1200 TEXAS AVENUE	HOUSTON	1.7.	77002
US PENITENTIARY-POLLOCK	115 131:7167845	POB 1000 1000 AIR BASI! RD	POLLOCK	LA	71467
ALEXANDER NININGER SVIIZ	195 1117171589	8401 W CYPRESS DR	PEMBROKE PINES	FI.	33025
CLUFORD CHESTER SIMSSVIIZ	195 BF8568909	4419 TRAM ROAD	SPRINGFIELD	¥¥.	32404
D.T. JABSON ST NII SVH2	195 HF8646816	21281 GRAYTON TERRACIE	PORT CHARLOTTE	FL	33954
HARLINGEN VA OUTIT CLINIC	115 13119206714	2106 TREASURE HILLS BLVD	IIARLINGEN	TX	78550
INS DETENTION FACILITY	115 B12613885	BUENA VISTA ROAD	BAYVIEW	TX	78566
IMMIGRATIONS & CUSTOMS VA	115 BISS61367	ISBSO EXPORT PLAZA DRIVE	HOUSTON	TX	77032
IMMIGRAT&CUSTOMS/PEARSALL	115 BI9144457	566 VETERANS DRIVE	PEARSALL.	77.3	78061
JAMES A HALEYIVA MED I/P	195 BJ0413839	13000 BRUCE B DOWNS HEVD	TAMPA	FL	33612
FCI MARIANNA	195 IIM1291347	3625 FCI ROAD	MARIANNA	379.	32446
NORTH CENTRAL FED CLINIC	115 BN9966500	17440 HENDERSON PASS	SAN ANTONIO	73	78232
POARCH BAND-CREEK IND HIS	195 [11] 1332080	5XLLJACK SPRINGS RD	ATMORE:	ΛL	36502
CHITIMACHA HLITHÆHUMAN HIS	115 BP7040176	3231 CHITIMACHA TRAIL	CHARENTON	I.A	70523
SNII BVAMC/BAY MINETT SVII2	195 BS7636698	300 PAULKNER DRIVE	DAY MINETTE	۸L	36507
SW LA WAR VETERANS HOME	115 0359016379	1610 EVANGELINE HWY	JENNINGS	LA	70546
USPIIS IMMIGRATION CUSTOMS	115 BU9827140	1001 WELCH STREET	TAYLOR	TX	76574
USPHS MEDICAL CLINIC BICE	115 BU9834640	1800 INDUSTRIAL DRIVE	ILLIIV(INOMYAR	XT	78580
V A OUTPATIENT CLINIC	195 BV0255706	551 NATIONAL HLTTI CARE DR	DAYTONA BEACH	FL	32114
VA MAYAGUEZ OUTPAT CLINIC	195 870366787	STATE RD 2, KM. 156.2	MAYAGUEZ	1.84	680
VA MC PHCY OAPPENSACOLA	195 1170464761	312 KI:NMORE: RD / RM 1G222	PENSACOLA	FL.	32503
VA OF CLIN-CORPUS CHRISTI	115 HV 1253739	5283 OLD BROWNSVILLE ROAD	CORPUS CHRISTI	TX	78405
VA OF CLINIC-FRANK TEJEDA	115 BV1276206	5788 ECKHERT ROAD	SAN ANTONIO	TX	78240
VA PONCE OUTPAT CLINIC	195 BV1501700	IOIO PASEO DEL VETERANO	PONCE	PR	716
VA OUTPATIENT CLINIC	115 BV2325644	1301 WEST FRANK STREET	LUFKIN	TX	75904
VA ON CLINIC - AUSTIN	115 BV2524913	2901 MONTOPOLIS DRIVE	AUSTIN	TX	78741
VA M/C PHCY O/P MOBILE	195 BV2658687	1504 SPRINGHILL AVE#1504	MODILE	ΛL	36604
VA OUTPAT CLINIC-MCALLEN	115 BV2813182	2101 S COLONEL ROWE BLVD	MCALLEN	TX	78503
VA OUTPATIENT CLINIC	195 BV3465970	1607 ST JAMES COURT	TALLAHASSEE	97 Q_	32308
VA OUTPATIENT CLINIC	195 BV4345319	9912 LITTLE ROAD	NEW PORT RICHEY	FL.	34654
VA OUTPATIENT CLINIC	195 BV6325852	2900 VETERANS WAY	VIERA	FL	32940
VA COMM BASED OUTPAT CLIN	195 BV7743241	ROUTE #2 BAY 15-17	KINGSHILL	VI	850
NW LA WAR VETERANS HOME	115 FN0209103	3130 ARTHUR RAY TEAGUE PK	DOSSIER CITY	LA	71112
SELA WAR VETS HOME	115 FS0318685	4080 WEST AIRLINE HIGHWAY	RESERVE	LA	70084
USPIES IMMIGRATION JENA	115 FU0594350	830 PINEHILL ROAD	JENA	I.A	71342
SUBSTANCE DEPEND TREAT PR	115 PV0122161	2002 HOLCOMBE BLVD	HOUSTON	TX	77030
VA MEDICAL CIR DETOX	115 RS0222480	7400 MERTON MINTER BLVD	SAN ANTONIO	ΪX	78229
The State of	A A M. And A A L. Deck Strategic Strategics.	<ul> <li>උපද සහ උපද ප්රවිධ , ම ප්‍රීමාධ වෙසිවිම ම පිළිබඳ ප්‍රීමාධ විසින් සිට ප්‍රවිධ කිරීම ප්‍රීමාධ සිට ප්‍රීම සිට ප්‍රීමාධ සිට ප්‍රීම සිට ප්‍රීමාධ සිට ප්‍රීම සිට ප්‍රීමාධ සිට ප්‍රීම සිට සිට ප්‍රීමාධ සිට සිට සිට සිට සිට සිට සිට සිට සිට සිට</li></ul>	.vc= mv 7	V 20 W	. 11000

Appendix C - Sales Accounts at Lakeland and Conroe Facilities authroized by DEA as an exception to Paragraph II.1(d). (Lakeland DC Code = 195/Conroe Code = 115)

VA FOXTROT

195 RV0329688 401 GILLIS DRIVE

ORLANDO

W.

32824

Case 3:17-cv-01362 Document 1509-3 Filed 01/12/22 Page 212 of 220 Page 10 #. 72771

LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.

700 THIRTEENTH STREET, N.W. RESTRIPON WASHINGTON D. C. 20005-5929 12021 737 - 5500 CAPCIBLE T 12021737-9329

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• AQ89" (Rev.: )/20/2005) [MD Rev. 01/29/2002] Surpoens in a Criminal Case

# United States District Court

FOR THE DISTRICT OF MARYLAND

ľ	MMTED	STATES	OF	AMERICA

V.

SUBPOENA IN A CRIMINAL CASE

Case Number:

Steven A. Sodipo, etal

BEL-06-0444

TO:

Mr. Garry Adam c/o McKesson Drug Company 7721 Polk Avenue Landover, MD 20785 Fax: 415-983-9369

YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below, or any subsequent place, date and time set by the court, to testify in the above referenced case. This subpoena shall remain in effect until you are granted leave to depart by the court or by an officer acting on behalf of the court.

PLACE	COURTROOM
United States Courthouse	70
101 West Lombard Street	DATE AND TIME
Baltimore, Maryland 21201	June 9, 2008
	10:00 am

☐ YOU ARE ALSO COMMANDED to bring with you the following document(s) or object(s):

U.S. MAGISTRATE JUDGE OR CLERK OF COURT	DATE 🔥
U.S. MAGISTRATE JUDGE OR CLERK OF COURT  Felicia C. Cannon, Clerk  Felicia C. Cannon, Clerk	May 29, 2008
(By) Dcputy Clerk	*
ATTORNEY, SINAME ARPRESS AND CHOOSE NUMBER:	
Assistant U. S. Attorney, 36 South Charles Street, 49 Floor, Baltimore, Maryland 21201 (410) 209-4800	

Department of Justice Office of the United States Attorney District of Maryland 36 South Charles Street Fourth Floor Baltimore, MD 21201 Fax (410) 962-0122 Phone (410) 209-4800



Rod J. Roseustein United States Attorney

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John Gilbert

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June 6, 2008

TO:

Honorable Mary Ellen Bittner

FAX NO.:

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Linden Barber

(202) 307-4946

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D'A ARAMANDA & STIELP & MANNHA

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

In the Matter of

McKesson Corporation d/b/a McKesson Drug Company

Docket Nos. 06-66 08-14

### ORDER TERMINATING PROCEEDINGS

On June 6, 2008, counsel filed a joint motion to terminate the proceedings in the above-captioned matters on grounds that the parties have entered into an agreement that resolves the issues in both of the pending matters.

Inasmuch as it appears that these proceedings are now moot, it is

ORDERED that all proceedings in the above-captioned matters before the
undersigned be, and they hereby are, terminated.

Dated: June 6, 2008

Mary Ellén Bittner

Administrative Law Judge

### CERTIFICATE OF SERVICE

This is to certify that the undersigned, on June 6, 2008, caused a copy of the foregoing to be delivered via interoffice mail to counsel for the Government, Wayne Patrick, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, postage paid, to counsel for Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street, N.W., Suite 1200, Washington, D.C. 20005.

Thomas 'Skip' Mark

Attorney Advisor to Mary Ellen Bittner

Administrative Law Judge

# UNITED STATES DEPARTMENT OF JUSTICE Drug Enforcement Administration

COURTED TO THE PROPERTY OF THE	,000	
In The Matter of	)	
	)	
McKesson Corporation	)	Docket Nos. 06-66
d/b/a McKesson Drug Company	)	and 08-14
	_)	

# JOINT MOTION TO TERMINATE

McKesson Corporation (Respondent), through the undersigned counsel, respectfully submits this Joint Motion to Terminate the hearing and any further proceedings in the above captioned matters. As grounds for this request, the parties state that on May 2, 2008, Respondent and the Government entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement that resolves both of the pending matters, Docket Nos. 06-66 and 08-14. The undersigned has discussed this motion with D. Linden Barber, Esq. and Wayne Patrick, Esq. counsel for the Government in these matters. The Government joins in the motion.

Respectfully submitted,

John A. Gilbert/Jr.

Hyman, Phelps & McNamara PC 700 Thirteenth Street, N.W.

Washington, D.C. 20005

(202) 737-5600

(202) 737-9329 (Fax)

Counsel for McKesson Corporation

Dated: June 6, 2008

# CERTIFICATE OF SERVICE

This is to certify that the undersigned, on June 6, 2008, caused a copy of the foregoing to be delivered by facsimile with a confirmation copy by regular mail to The Honorable Mary Ellen Bittner U.S. Department of Justice, Drug Enforcement Administration, 600 Army Navy Drive, Arlington, Virginia, 22202, and copies to be delivered by facsimile and regular mail to:

D. Linden Barber
Chief, Regulatory Section
Office of Chief Counsel
Drug Enforcement Administration
600 Army/Navy Drive
Arlington, Virginia 22202

Kathleen McKinley